Program Description Animal Care and Use Program

US Navy Marine Mammal Program

Space and Naval Warfare Systems Center Pacific (SSC Pacific)

49620 Beluga Rd. San Diego, CA 92152-6505

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Table of Contents

Section 1.	Introduction	1
Section 2.	Description	7
I. Anima	al Care and Use Program	7
A. Pro	gram Management	
1.	Program Management Responsibility	
a.	The Institutional Official	7
b.	The Attending Veterinarian	7
c.	Collaborations	9
2.	Personnel Management	9
a.	Training and Education	
	i. Veterinary and Other Professional Staff	
	ii. Animal Care Personnel	
	iii. The Research Team	15
b.	Occupational Health and Safety of Personnel	
	i. Hazard Identification and Risk Assessment	
	ii. Facilities, Equipment and Monitoring	
	iii. Personnel Training	
	iv. Personal Hygiene	
	v. Animal Experimentation Involving Hazards	
	vi. Personal Protection	
	vii. Medical Evaluation and Preventive Medicine for Personnel	
c.	Investigating and Reporting Animal Welfare Concerns	31
	gram Oversight	32
1.	The Role of the IACUC/OB	
a.	IACUC/OB Composition and Function	
b.	Protocol Review	
c.	Special Considerations for IACUC/OB Review	
	i. Experimental and Humane Endpoints	
	ii. Unexpected Outcomes that Affect Animal Well-being	
	iii. Physical Restraint	
	iv. Multiple Survival Surgical Procedures	
	v. Food and Fluid Regulation	
	vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances	
	vii. Field Investigations	
	viii. Agricultural Animals	
•	ix. Animal Reuse	
2.	Post-Approval Monitoring	
	al Environment, Housing and Management	
	mal Environment	
1.	Temperature and Humidity	
2.	Ventilation and Air Quality	
3.	Life Support Systems for Aquatic Species	
4.	Noise and Vibration	
B. Animal Housing (All terrestrial, flighted, and aquatic species)		
1.	Primary Enclosures.	
2.	Environmental Enrichment, Social and Behavioral Management Enrichment	
a.	EURICHIII EUR	4 /

i

	b. Social Environment	
	c. Procedural Habituation and Training of Animals	43
	d. Enrichment, Social and Behavioral Management Program Review	44
	e. Sheltered or Outdoor Housing	
	f. Naturalistic Environments	44
C.	Animal Facility Management	45
1.	Husbandry	45
	a. Food	45
	b. Drinking Water	
	c. Bedding and Nesting Materials	
	d. Miscellaneous Animal Care and Use Equipment	
	e. Sanitation	
	f. Waste Disposal	
	g. Pest Control	
	h. Emergency, Weekend and Holiday Care	
2.		
	a. Identification	
	b. Record Keeping	
	c. Breeding, Genetics and Nomenclature	
III.	Veterinary Care	
A.	Animal Procurement and Transportation	
1.	· · · · · · · · · · · · · · · · · · ·	
2.		
	T	
ъ. 1.		
2.	·	
3.		
4.		
C	Clinical Care and Management.	
C. 1.		
2.		
3.		
3. 4	Drug Storage and Control	
D.	Surgery	
ъ. 1.	~_ ·	
2.		
3.		
3. 4.	c	
4. 5.	Intraoperative Monitoring	
5. 6.	1	
о. Е.	Postoperative Care Pain and Distress	
F.	Anesthesia and Analgesia	
G.	Euthanasia	
IV.	Physical Plant	
A.	Location and Construction Guidelines.	
В.	Functional Areas and Operations	
1.		
2.		
3.	System Malfunctions	/0

ii 2/11

4.	Storage Areas	71
5.	Facilities for Sanitizing Materials	
	ecial Facilities	
1.	Specialized Types of Animal Housing	
2.	Surgery	
3.	Other Specialized Animal Use Facilities	. 72
4.	Other Animal Support Facilities	. 73
	curity and Access Control	

Appendices

- 1. Organizational Charts
- 2. Animal Usage Form B
- 3. Summary of Animal Housing and Support Sites
- 4. Line Drawings
- 5. Medical Evaluation Form
- 6. IACUC/OB Membership Roster
- 7. Blank IACUC/OB Protocol Form
- 8. IACUC/OB Minutes
- 9. IACUC/OB Periodic Report
- 10. Heating, Ventilation and Air Conditioning (HVAC) System Summary
- 11. Aquatic Systems Summary
- 12. Primary Enclosures and Animal Space Provisions
- 13. Cleaning and Disinfection of the Micro- and Macro-Environment

iii 2/11

Program Description

Link to <u>Instructions for Completing and Submitting the Program Description for the Institutional</u>
Animal Care and Use Program

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

Unit: US Navy (USN) Marine Mammal Program (MMP). Parent Organization: Space and Naval Warfare Systems Center Pacific (SSC Pacific). AAALAC International file number 000887.

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

SSC Pacific is a full-spectrum research, development, test, and evaluation (RDT&E) laboratory serving the Navy, Marine Corps, and other DoD and national sponsors within its mission, leadership assignments, and prescribed functions. It is unique in its animal population, use, and application. SSC Pacific's US Navy Marine Mammal Program (Code 71005) and the Biosciences Division (Code 71500) operates, trains, and cares for over 100 marine mammals for national defense purposes, in accordance with the provisions of Section 7524 of Title 10, United States Code (1 FEB 2010), SECNAVINST 3900.41G (24 JAN 2011), the Animal Welfare Act, and a plethora of various other statutes and regulations governing marine mammal care, use, and administration. SECNAVINST 3900.41G names the Biosciences Division at SSC Pacific as the lead laboratory for all Navy-sponsored programs that involve the procurement, transport, and maintenance of marine mammals. This program provides trained military working animals to the Navy. Currently, three operational Fleet Marine Mammal Systems (MMS) fulfill operational requirements and needs. All MMS are valuable, quick response, transportable assets to the Expeditionary Forces Mine Warfare and Maritime Defense Programs. As a secondary mission, investigators conduct operational and biomedical science research to define the requirements, capabilities and limitations of marine mammals in the above applications as well as to enhance their health and performance operationally. Investigations on the environmental impact of global DoD activities on the health and welfare of free-ranging and captive marine mammals are also conducted.

C. Note that <u>AAALAC International's three primary standards</u> are the <u>Guide for the Care and Use of Laboratory Animals (Guide</u>), NRC, 2011; the <u>Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide</u>), FASS 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use

program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the <u>Guide</u> and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the <u>Ag Guide</u> for agricultural animals used in agricultural research and teaching. In the European Union, the standards applied might be the <u>Guide</u>, ETS 123, Directive 2010/63, and any country-specific regulations.

The <u>Guide for the Care and Use of Laboratory Animals</u>, NRC (2011) is the primary standard used for the program. Other regulations utilized include 9 CFR Chapter 1 Subpart A of the Animal Welfare Act (Nov 2013), SECNAVINST 3900.41G (24 Jan 2011) and DOD Instruction, "Use of Animals in DoD Programs".

While the facility is not subject to USDA inspections, the center does hold a USDA registration number, 93F-005, and submits an animal use report, APHIS form 7023, annually. The Navy Marine Mammal Program is continuously under the scrutiny of federal and public special interests groups as well, to include oversight by the US Navy Bureau of Medicine and Surgery (BUMED).

The Biosciences Division Head has established an Animal Safety Committee (ASC). The purpose of the ASC is to review changes to hardware, methodologies and applications of training employed with working animals to ensure the safest hardware and equipment designs and methodologies practical are being employed. In particular, new hardware and applications are reviewed prior to implementation and existing hardware to be utilized in new areas or greatly expanded in applications, such as transfer from use at SSC Pacific to the fleet systems, are reviewed. This committee also reviews accidents involving animals. The ASC chair reports directly to the Division Head.

D. Describe the organization and include an organizational chart or charts (as an Appendix/Appendices) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (Note: For individuals whose information is publically available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, the

2/11

organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

DVM, PhD, DACZM, Senior Scientist for Animal Care and Research, is appointed by the head of the Biosciences Division, and has senior oversight responsibility for all animal care and use policy. He maintains direct line reporting authority to the Assistant Secretary of the Navy (Research, Development, and Acquisition) under SECNAVINST 3900.41G. (b)(6); (b)(7)c MBA, Director, Navy Marine Mammal Program, serves as the Institutional Official. The following personnel hold supervisory positions: (b)(6); (b)(7)c PhD, Head, Biosciences Division and Marine Mammal Scientific and Veterinary Support Branch; (b)(6): (b)(7)c Lab Operated Systems Project Manager; and (b)(6): (b)(7)c Head of Marine Mammal Systems Technical Support Branch. The Attending Veterinarian, (b)(6): (b)(7)c reports directly to the Head of Biosciences Division and the Institutional Official. The Attending Veterinarian oversees a staff of seven contract civilian veterinarians, in addition to three Army Veterinary Corp Officers (VCOs), and promulgates animal care and use policies. Five Army Animal Care Specialists, six contract civilian animal care technicians, and a staff of contract administrative/laboratory personnel assist them. Twenty seven civil service biological technicians supervise animal training, including approximately 150 contract animal trainers.

The IACUC is composed of ten voting members, including the chair appointed by the IO (Director, Navy Marine Mammal Program). The IACUC also includes two alternate members, a non-voting administrator, and two consultants. The IACUC and AV report directly to the IO, and all components work together to ensure the highest quality animal care and use program.

Organizational charts are provided as Appendix 1. Details of the organization may be found at: https://blog.spawar.navy.mil/manpower/org-chart.html

The U.S. Navy Marine Mammal Program website may be found at: http://www.spawar.navy.mil/sandiego/technology/mammals

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

(b)(6); (b)(7)c MBA
Director, Navy Marine Mammal Program, Institutional Official
SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC Code 71005

(b)(6); (b)(7)c DVM, MS, MPVM, DACVPM
Chair, IACUC
SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC Code 71510

(b)(6); (b)(7)c MS
Administrator, IACUC

SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC code 71510

(b)(6); (b)(7)c DVM

Attending Veterinarian

SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC code 71510

(b)(6); (b) PhD

Head, Biosciences Division and Marine Mammal Scientific and Veterinary Support Branch

SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC code 71500

(b)(6); (b)(7)c DVM, PhD, DACZM

Senior Scientist for Animal Care and Research

SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC code 71510

(b)(6); (b)(7)c

Head, Safety & Environmental Office SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC code 83500

(b)(6); (b)(7)c

Commanding Officer

SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC

(b)(6); (b)

Public Affairs Office

SPACE AND NAVAL WARFARE SYSEMS CENTER PACIFIC code 85000

(b)(6); (b)(7)c will participate in the site visit. A courtesy visit to the Commanding Officer may be arranged upon request.

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the <u>instructions</u>, please complete one of the animal use forms included with this outline or provide the information requested in a similar format as an appendix.

This program is unique in its animal population, use, and application. The primary animal activity is the training, care, and operational deployment of military working marine mammals. Funded research is directed at: determining and defining animal echolocation capabilities for underwater object detection, localization, and marking; potential environmental effects of underwater sound on marine mammals; development of computational models of dolphin echolocation for inclusion in the development of hardware systems to eventually replace animal use as object detectors; and defining the requirements, capabilities, and limitations of marine mammals used for operational fleet marine mammal systems (MMS). Several non-invasive protocols are ongoing to advance and improve the knowledge, methods, and equipment of navy marine mammal veterinary care and to monitor the impact of human activities on marine mammals. The current active protocols (11) and principal investigators (seven) are detailed on the animal use form B, in appendix 2.

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

Animal research programs at the MMP include investigations of dolphin echolocation to develop models for navy sonar processing and studies of dolphin and sea lion hearing and physiology that inform navy environmental compliance efforts. In addition, veterinary research is pursued to benefit the health and welfare of the navy's working animals. The point of contact for these programs is (b)(6); (b)(7)c

STUDY FUNDING SOURCE Dolphin Nephrolithiasis Office of Naval Research Dolphin Metabolic Syndrome Office of Naval Research Marine Mammal Hearing and Vision Office of Naval Research/Navy Living Marine Resources Dolphin Metabolism and Kidney Office of Naval Research Dolphin Sea Lion Anesthesia Ventilators Office of Naval Research Sea Lion Pulmonary Function Navy Fleet **Dolphin Commensal Probiotics** Office of Naval Research Marine Mammal Open Ocean Hearing Defense Advanced Research Projects Agency **Defense Advanced Research Projects** Marine Mammal Neuroplasticity Training Agency Humpback Whale Hearing Range Audiometry Navy Fleet Forces Command **Dolphin Hearing Temporary Shifts** Navy Living Marine Resources

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.

A subset of the Navy's military working marine mammals support the Strategic Weapons Facility Atlantic and Strategic Weapons Facility Pacific. Oversight is maintained by the MMP, Biosciences Division, Senior Scientist for Animal Care and Use, Attending Veterinarian, US Army VCOs, and the Animal Safety Committee. These animals and their facilities are not included in the program application because they do not participate in research programs.

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the

site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

There are no contracted facilities.

J. Note other relevant background that will assist reviewers of this report.

SSC Pacific serves as the DoD equivalent to the Military Working Dog Center for Navy Working MMS. Center scientists, veterinarians, and animal trainers have made numerous contributions to the improvement of the knowledge, methods, and equipment of marine mammal science, medicine, and husbandry over the past fifty years. These accomplishments have been documented in over 1100 open literature publications and numerous presentations (See Annotated Bibliography of Publications by the US Navy Marine Mammal Program at http://nmmf.org/resources/marine-mammal-annotated-bibliography/). The resulting technologies and advancements are available to, and have been applied by, public and private institutions worldwide to improve marine mammal care and welfare. From the earliest days of the program, navy marine mammal researchers have emphasized the need for enlisting the animal's cooperation in the investigations conducted so that they may be done in open water settings. This has led to greatly improved humane handling and care of marine animals. The techniques pioneered by the US Navy are now widely adopted.

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [Guide, pp. 13-15]

a. The Institutional Official [Guide p. 13-14]

Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The SSC Pacific IACUC membership is appointed by (b)(6); (b)(7)c Director, Navy Marine Mammal Program, who serves as the Institutional Official.

The IACUC prepares and submits evaluation reports following semi-annual program reviews and facility inspections, noting significant deficiencies, and provides a copy of the inspection report to the IO. The IACUC and AV make recommendations to the IO regarding any aspect of the animal program, facilities, or personnel training, and notify and consult with the IO in the event of any suspended activity, serious non-compliance, or serious deviation from regulations.

b. The Attending Veterinarian [Guide, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. For each veterinarian associated with the program (including private practitioners), provide the veterinarian's name(s), list responsibilities, and how the veterinarian is involved in monitoring the care and use of laboratory animals. If employed full-time by the institution, note the percentage of time devoted to supporting the animal care and use program of the institution. If employed part-time or as a consultant, note the frequency and duration of visits.

Veterinary care is provided to all Navy marine mammals by a team of nine full-time and five part-time veterinarians. This team reports to (b)

PhD, Head, Biosciences Division Included on this team(s)(b)(6);

Senior Scientist for Animal Care and Research, a lea(b)(7)(6) the fields of marine mammal care, medicine, surgery, and research for 40 years. He holds senior oversight responsibility for all center animal care and use policies and is responsible for the training and guidance of all center animal care personnel.

Responsibilities: The veterinary staff provides continuous medical support to animals housed at all facilities, and provides support for all activities that require animal transport. Veterinary responsibilities include provision of care and treatment for clinical cases, herd health and preventive

medicine program, disease surveillance, emergency medicine, deployment medicine, and research to improve the health of the navy's marine mammals. While the primary mission of the Navy's Marine Mammal Program is providing trained and fully medically ready animals for the Fleet Marine Mammal Systems, all veterinarians participate in providing care and support for research programs.

Full-time Veterinarians (100%) Civilian GS and Contract

Military (Army):

(b)(6); (b)(7)c

(b)(6); (b)(7)c

In addition to clinical care as above, the US Army staff is responsible for the marine mammal subsistence program (seafood safety from procurement and storage to handling and feeding), conducting DoD working animal facility inspections, and environmental monitoring, the occupational health and safety program, and regulatory reporting requirements.

Part-time relief and specialty veterinarians:

,(b)(6); (b)(7)c provides approximately 10% relief support when there are absences of full time veterinarians.

(b)(6); (b)(7)c radiologist, (b)(6); (b)(7)c anesthesiologist, and (b)(6); are contracted on an as needed, case by case basis and may account for 5% per year.

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a direct role in the provision of veterinary care and describe their responsibilities. An organizational chart depicting the reporting relationship between these individuals and the Attending Veterinarian should be included as an appendix.

Full time veterinary support is provided by six civilian animal technicians and five Army Animal Care Specialists. All technicians report directly or indirectly to the Attending Veterinarian.

There are three part time veterinary technicians that provide 10% support annually.

The program often consults with other specialists such as veterinary ophthalmologists, veterinary dentists, human interventional radiologists, human urologists, infectious disease specialists, etc., in order to provide

the highest quality care. These specialists provide guidance and technical skills related to their specialty, and consult directly with the Attending Veterinarian.

c. Collaborations [Guide, p. 15]

Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations (i.e., collaborations).

The USN MMP maintains animal care and use responsibility, ownership, and IACUC oversight for all animals involved in research.

2. Personnel Management

a. Training and Education

Describe how the IACUC/OB provides oversight and evaluates the effectiveness of training programs. Describe how training is documented.

Training requirements are outlined in IACUC SOP 9 "Initial Training of U.S. Navy Marine Mammal Program IACUC Members." Veterinary staff, animal care personnel, research staff, and IACUC members all receive regular formal and informal training on marine mammal biology, medicine, science, and training techniques, to ensure animal well-being and high quality science. The Attending Veterinarian, Senior Scientist, and Biological Technicians provide supervision of these training programs. Quarterly Animal Care Briefs are conducted for all staff on topics such as animal welfare and regulations, emergency response, occupational health, zoonoses, the IACUC and the Animal Safety Committee. On the job training is required and formally documented for all incoming animal care personnel and animal trainers, and regular refreshment training is provided. Formal training is documented through sign-in sheets and credentialing records, and are maintained in the individual's personnel record. Individualized informal training is also utilized extensively. IACUC members receive eight hours of initial formal training as well as semi-annual training. PIs also have training requirements. IACUC member and PI training records are maintained with the IACUC administrator.

i. Veterinary and Other Professional Staff [Guide, pp. 15-16] Provide name and credentials of veterinary and other professional staff, including the veterinary personnel listed above, and describe their qualifications, training, and continuing education. Please do not provide curriculum vitae of personnel.

(b)(6); (b)(7)c DVM, PhD, DACZM
(b)(6); (b)(7)c received his DVM, Texas A&M University, 1960, and PhD (neurobiology), University of Cambridge, 1973. He is a diplomate of the American College of Zoo Medicine. (b)(6); (b)(7)c has published 270 papers, articles and books concerning scientific research and veterinary care of marine mammals, including one book (b)(6); (b)(7)c for

general readers. He served as editor of a six-volume series HANDBOOK OF MARINE MAMMALS, Academic Press and of the first general veterinary medical reference text for marine mammals: MAMMALS OF THE SEA: BIOLOGY AND MEDICINE. He has published in SCIENCE, NATURE, SCIENTIFIC AMERICAN, JAVMA and many other peerreviewed journals. He is the Founding President and Honorary Life Member of the International Association for Aquatic Animal Medicine (IAAAM) and a Charter Member of The Society for Marine Mammology (SMM). In 2009, he received the Kenneth S. Norris Life Time Achievement Award from the Society for Marine Mammalogy.

(b)(6); (b)(7)c, DVM

(b)(6); (b) received his DVM from Iowa State University College of Veterinary Medicine, 1990. (b)(6); (b) began working with marine mammals in 1987 at Kewalo Basin Marine Mammal Laboratory in Honolulu, Hawaii as a student intern. He then went to Marine Life Oceanarium in Gulfport, Mississippi where he worked as an animal handler and assisted with dolphin collections in the Gulf of Mexico. He has also worked with staff veterinarians at the Mayo Clinic, Rochester, Minnesota, in the comparative medicine research department. In 1990 (b) began working as staff veterinarian and research coordinator for (6); Marine Life Oceanarium/Marine Animal Productions. In 1993 Dr. Jenseh served as an associate veterinarian in a small and exotic animal practice in Orange County, Florida and served as attending veterinarian for The Living Seas, EPCOT, Walt Disney World. In 1995 (b)(6): (b) began working with the US Navy's Marine Mammal Program (MMP) in San Diego, California, as a consulting and contract veterinarian and in 1998 became an employee of the Department of Defense continuing veterinary support as a civil servant. In 2003 (b)(6): (b) provided clinical care support to the MK7 and MK8 marine mammal systems serving in Iraq during Operation Iraqi Freedom. Continued support to Operation Enduring Freedom was provided to the MK 6 marine mammal systems at Naval Support Activity Bahrain. (b)(6); (b) provided oversight for the Navy's dolphin breeding program and currently serves as Managing

(b)(6); (b)(7)c DVM

Veterinarian for the MMP.

(b)(6); (b) received her DVM from Tufts University, 1999.

During clinical training at Tufts, (b)(6); (b) received specialized aquatic medicine training at several institutions including the MMP, Sea World of Florida, New England Aquarium, North Carolina State University College of Veterinary Medicine, and the Marine Biological Laboratory (MBL) in Woods Hole. She also completed research training at Tufts and the MBL, resulting in a veterinary thesis that investigated the toxicological effects of pollutants on the developing nervous system of an aquatic animal model. After receiving her DVM, she continued to specialize in aquatic medicine and research, and completed an Aquatic Medicine Internship at the New England Aquarium. Following the internship, she was awarded a National Research Council Associateship at the MMP, where a major research

effort was successfully launched bringing together a multi-institutional collaboration of scientists and resulted in development of the first marine mammal DNA vaccine. She has provided clinical care to Navy dolphins and sea lions since 2001, and has provided direct support for marine mammal system operations involved in OIF, OEF, Blue Game and CJTFX. Her current clinical focus areas are preventive medicine and diagnostic imaging of marine mammals.

(b)(6); (b)(7)c DVM, DACZM

(b)(6); (b)(7)c attended veterinary school at Purdue University and graduated in 2004. She earned diplomate status in the American College of Zoo Medicine in 2016. After graduation, she completed a 1-year veterinary internship at VCA Emergency Animal Hospital and Referral Center in San Diego, CA. She then spent 2 years at Mystic Aquarium researching brucellosis in marine mammals and as a clinical veterinarian. She then completed a 3-year aquatic animal veterinary residency at the University of Florida. Her involvement with the Navy Marine Mammal Program over the years has included Brucella research, a veterinary preceptorship, and more recently the SmartPill project.

(b)(6); (b)(7)c DVM

(b)(6); (b) received her Doctorate in Veterinary Medicine from the University of California, Davis in 2008. She began working with marine mammals in 1998 at the Monterey Bay Aquarium as a sea otter trainer and veterinary assistant. During this time she also worked as a veterinary technician in both emergency and avian exotic medicine practices. During veterinary school, (b)(6); (b) worked as a large animal nurse and completed veterinary student rotations at the U.S. Navy's Marine Mammal Program and Marine Mammal Center, Sausalito, California. After graduating from veterinary school, she completed a rotating internship in small animal medicine and surgery in Santa Rosa, California.

(b)(6); (b)(7)c **DVM**

(b)(6); (b)(7)c is a clinical veterinarian for the National Marine Mammal Foundation. She has been a marine mammal veterinarian for 6 years. After graduating from the Ohio State University College of Veterinary Medicine in 2005. Betsy completed a Post-Doctoral research associateship with the National Research Council and The Navy Marine Mammal Program in 2008, and continues to work with the Navy today. Her top clinical interests include ophthalmology, cytology and interventional radiology.

(b)(6); (b)(7)c, **DVM**

(b)(6); (b)(7)c is a clinical veterinarian for the Navy's Marine Mammal Program through the National Marine Mammal Foundation. She received her Bachelor's degree in Zoology with a minor in Wildlife Ecology and Conservation in 2004. In 2008, she received her Doctor of Veterinary medicine degree from the University of Florida. (b)(6); (b) went on to complete an internship in small animal medicine and surgery at

Affiliated Veterinary Specialists in Maitland, Fl. In 2009, (b)(6); (b) received a National Research Council Associateship Grant to validate pool-side tests for diagnosing failure of passive transfer of immunity in neonatal bottlenose dolphins, while training with the Navy's Marine Mammal Program as a Post-Doctoral clinical veterinarian. (b)(6); (b)(7)c current interests are in neonatal immunology, molecular diagnostic development, and anesthesia and surgery in marine mammals.

(b)(6); (b)(7)c **DVM**

(b)(6); (b)(7)c completed a veterinary externship with the National Marine Mammal Foundation in 2013 while completing his DVM at Tufts University. He also rotated through zoo, wildlife, and research facilities while attaining his veterinary degree. Following graduation, (b)(6); (b) completed a medicine & surgery rotating veterinary internship in Massachusetts and subsequently become a small animal emergency medicine clinician practicing in New York prior to returning to the Foundation in 2017 for a veterinary fellowship.

(b)(6); (b)(7)c **DVM**

(b)(6); earned her undergraduate degree in Animal Sciences from Cornell University in 2010. She attended University of Florida for veterinary school, earning her DVM and Certificate of Aquatic Animal Health, graduating in 2015. She then completed a one-year small animal rotating internship at Angell Animal Medical Center in Boston, MA. The following year, she completed a one-year veterinary fellowship at the Vancouver Aquarium, in Vancouver, BC, Canada, where she served as one of two clinicians for the aquarium's collection animals (cetaceans, pinnipeds, birds, fish, and other mammals), in addition to a variety of rescued marine mammals (approximately 180 animals per year). (b)(6): has previously completed a 4-month training internship with the Navy Marine Mammal Program, a one-month veterinary student externship with the National Marine Mammal Foundation, a 4-month marine mammal stranding internship at The Marine Mammal Center, Sausalito, CA, and a one-month veterinary student externship with The Marine Mammal Center.

(b)(6); (b)(7)c received her DVM from the University of Missouri-Columbia in 2004. She later received a Masters in International Agricultural Development in 2010 and Masters of Preventive Veterinary Medicine in 2014 both from the University of California, Davis. She earned diplomate status in the American College of Veterinary Preventive Medicine in 2010. Her military assignments have included veterinary and public health installation support in TX and Guam. She was a civil affairs battalion veterinarian for five years within both special operations and forces command. She has supported multiple joint military to military and mil to civ exercises and operations throughout Asia Pacific (Mongolia to Papua New Guinea and Diego Garcia to the Philippines) providing training and collaboration to veterinary counterparts in working canine

and equine medicine, surgery, and herd health, as well as military force health protection and food safety and defense.

(b)(6): (b)(7)c DVM, MPH, DACVPM

(b)(6); received her Bachelors degree in Economics from Harvard. She then concurrently earned her DVM and Master of Public Health degrees from University of Tennessee in 2012. She became a diplomate of the American College of Veterinary Preventive Medicine in 2016. As an Army Health Professions Scholarship recipient she completed a competitive veterinary student externship at the MMP. She served as the Section OIC for Fort Stewart Veterinary Services, GA. She managed two veterinary treatment facilities providing private and government owned animal care and food protection oversight for 52 military facilities and commercial audits. She also provided veterinary officer support to Guantanamo Bay, Cuba, and Soto Cano AFB, Honduras prior to being assigned to the MMP.

(b)(6); (b)(7)c **DVM**

(b)(6); (b)(7)c received his Bachelors degrees in Biology and Zoology from Colorado State University and then his DVM from CSU as well in 2013. He completed the US Army Veterinary Internship - FYGVE program at Joint Base Lewis McChord, WA and subsequently was assigned as a clinical veterinarian for Incirlik Air Base, Turkey supporting comprehensive medical and surgical care for military working dogs prior to being assigned to the MMP.

(b)(6); (b)(7)c DVM

(b)(6); (b) graduated with a DVM from the The Ohio State University, College of Veterinary Medicine in 1988. He completed an Exotic, Zoo, and Wildlife Medicine Internship at Kansas State University, 1996. He has 17 years experience as a Senior Staff Veterinarian at SeaWorld Orlando providing marine mammal medical and surgical services to the park's animals. He also assisted in the rescue, rehabilitation, and release of native aquatic and terrestrial species. He has also been the Chief Veterinarian for the San Antonio Zoological Gardens and Aquarium, TX and the Director of Veterinary Services and General Curator or Ocean World, Fort Lauderdale, FL. (b)(6); (b) has numerous publications and presentations on marine mammal medicine.

(b)(6); (b)(7)c DVM, CVA

(b)(6); (b) graduated with a DVM with honors from University of California, Davis in 2006. He received his CVA (certification in veterinary acupuncture) in 2015. He completed a rotating internship in emergency, surgery, and medicine in Santa Rosa, CA from 2006 to 2007. He has 10 years of experience as an emergency veterinarian at several referral and specialty hospitals. Since 2015 his focus has been on integrative and natural medicine.

(b)(6); (b)(7)c **DVM**, **DACVR**

(b)(6); (b)(7)c work with marine mammals began in 1998 as a trainer at Kewalo Basin Marine Mammal Laboratory in Honolulu, HI. While pursuing a veterinary degree at the University of California at Davis, she was a volunteer veterinary student at the Navy Marine Mammal Program in 2001 and returned in 2003 to conduct diagnostic imaging research with the NMMP funded by the Navy Research Enterprise Intern Program (ONR). She completed her veterinary degree in 2004 and subsequently pursued a small animal internship at Veterinary Medical and Surgical Group in Ventura followed by a three-year radiology residency at the University of Pennsylvania. Board-certified by the American College of Veterinary Radiology in 2008, (b)(6); (b) is the first veterinary radiologist to concentrate on aquatic animal diagnostic imaging. She served as radiologist to the Vancouver Aquarium from 2008-2011, and has been a radiologist with the National Marine Mammal Foundation since the fall of 2011. (b)(6); (b) provides clinical and research imaging support to the Navy Marine Mammal Program through the NMMF.

(b)(6); (b)(7)c DVM, MS, DACVA

(b)(6); (b)(7)creceived his veterinary medical training at Colorado State University in 1989. He served as clinical instructor for the Anesthesiology section at CSU for one year, then completed a Master of Science degree in veterinary physiology and pharmacology from Ohio State University. While completing his Master's thesis, (b)(6): (b) was a full-time consultant for Ethicon Endo-surgery in Cincinnati, gaining experience in endoscopic surgical techniques. In 1993 he accepted a clinical instructor position at the University of Florida in Gainesville and began an anesthesiology residency. By 1996 he was an assistant professor at UF and had successfully passed the board examinations of the American College of Veterinary Anesthesiologists. From Colorado through Florida, (b)(6): (b) has safely anesthetized a wide range of species, including but not limited to, cats, dogs, horses, cows, manatees. elephants, dolphins, and a North Atlantic Right Whale. He has also provided volunteer anesthesia support for Proyecto Danta Costa Rica, a Baird's Tapir Conservation project, as well as NOAA/NMML, Alaska Sea Life Center and Alaska Department of Fish and Game, Stellar sea lion, harbor seal and Bearded seal captures in Alaska. (b)(6): (b) also assisted in the startup of the first ever stand-alone magnetic resonance imaging facility for animals and operated a successful business providing specialty veterinary anesthesia care, pain management and education for private practice. (b)(6): (b) has been faculty at the Veterinary Colleges of Colorado State University, The Ohio State University, University of Florida, Ross University and Louisiana State University.

ii. Animal Care Personnel [Guide, p. 16]

Indicate the number of animal care personnel. Summarize their training, certification level and type, experience, and continuing education opportunities provided.

There are six civilian contract animal care technicians, five military animal care specialists and approximately 150 animal husbandry personnel.

Five US Army Animal Care Specialists and six civilian animal care technicians are assigned to support the animal care mission. The Army Animal Care Specialists attended formal training at an Army nine-week Basic Animal Care Specialist Course at either Fort Sam Houston, San Antonio, Texas or Walter Reed Army Institute of Research (WRAIR).

(b)(6) serves as the Non-Commissioned Officer in Charge (NCOIC) and has 11 years of military service and animal care experience. The other four Animal Care Specialists have two to six years of experience. Training for the Army and civilian technicians consists of extensive on the job training for tasks unique to the care and veterinary management of marine mammals. Numerous short courses are conducted such as radiation safety and hazardous material handling. Army Animal Care Specialists are encouraged to obtain laboratory animal certification (ALAT, LAT, LATG), and all technicians attend continuing education seminars as often as possible.

Daily feeding, care, and observation of the animals is provided by a staff of over 150 individuals. As part of the training regime, training personnel interact with the animals throughout the workday on a continuous basis. Training supervisors are senior government service and contract personnel. The contracts specify standards for animal training and care experience. Many of the training staff have been instrumental in the formation of the International Marine Animal Trainers Association (IMATA) and trainers regularly produce presentations for IMATA annual meetings as well as receiving innumerable awards for work with navy animals. Quarterly Animal Care Briefs are presented to all personnel (federal and contract) covering a wide variety of animal care topics and serving as ongoing personnel training. Informal training, individually with a veterinarian, is also extensively utilized as an ongoing resource for all animal care personnel. Contracted organization marine mammal training staff consists of Animal Training Supervisors, Animal Trainers and Animal Trainer Assistants. These positions have no universally accepted certification protocol, but instead are defined by levels of specific experience gained from outside work experience, schools, courses, and more importantly from specific experience gained under SSC Pacific's Biosciences Division. All trainers must complete the Orientation Curriculum and possess a nationally recognized current SCUBA diving certificate.

iii. The Research Team [Guide, pp. 16-17; 115-116; 122; 124]

1) Describe the general mechanisms, by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

Regularly scheduled Animal Care Briefs, training seminars, and presentations by visiting scientists described above are conducted and address all aspects of the humane treatment and scientific investigation of center marine mammals. Training and veterinary personnel conduct all animal care and maintenance in compliance with the standards for the care and maintenance of marine mammals defined by USDA APHIS. Principal investigators define experimental protocols; however, experienced personnel trained as described in above sections accomplish behavioral modification or "hands-on" requirements. Technical personnel, trainees, students, and visiting personnel working with animals for any reason are under the supervision of experienced trainers or veterinarians as appropriate. PI credentials are reviewed as part of research protocol approval and PIs receive training mandated by the IACUC as well.

a) Briefly describe the content of any required training.

Quarterly Animal Care Briefs cover topics such as the IACUC, zoonoses, emergency disaster preparedness, regulations, animal safety committee, and the Occupational Health Program.

Training and indoctrination of all animal care personnel occurs at the project level and is generally project specific given their unique aspects, differences in mammal species and behavioral development requirements. Standards have been established, however, to appropriately indoctrinate and train staff members in specific procedures and policies governing both common and special activities relating to marine mammal care. These standards have been promulgated in Biosciences Division Standard Operating Procedures 9 (Handling Marine Mammals), 10 (Animal Husbandry Behavior), 17 (Restraining a Sea Lion for Medical Care).

b) Describe the timing of training requirements relative to the commencement of work.

All research is conducted under the direct supervision of veterinary staff or experienced biotechnicians and animal trainers. Any minor surgery, anesthesia, or procedure required in a protocol is directly performed by the veterinary staff under supervision of the Attending Veterinarian. All employees complete training requirements prior to the commencement of work and consult directly with the attending veterinarian.

c) Describe continuing education opportunities offered.

Research staff attend scientific conferences as often as possible and relevant to their field of study. In-house training opportunities such as boat operation, marine mammal behavior,

and various equipment operations are offered. New employees are required to attend an Animal Handling Course. Records of training are maintained in each individual's personnel file.

Marine mammal training staff undergoes periodic in-house refresher training and indoctrination as described above. Presentations cover a variety of topics and subject matter relevant to procedures in the care and training of marine mammals and information of general interest within the marine mammal community. Attendance is recorded in the individual's training record. Additionally, some staff members possess formal schooling and educational backgrounds with emphasis in marine mammal care and training such as the applicable undergraduate marine biology degree, U.S. Navy's Marine Mammal Handlers' course and the A.S. degree program in Exotic Animal Training and Management offered by Moorpark College.

Continuing education for the Army and civilian technicians consists of training on new equipment and procedures on a regular basis. They are encouraged to attend conferences and webinars to increase their knowledge base. Career enhancement training to include college, correspondence, and leadership courses are offered through the military.

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel. Who determines that personnel are qualified and trained for surgical procedures? What role does the Attending Veterinarian and IACUC/OB have in this determination? [Guide, pp. 115-116]

Marine mammals at the MMP do not undergo major surgery or euthanasia as part of any research protocol. Any minor surgery, anesthesia, or procedure required in a protocol is directly performed by the veterinary staff under supervision of the Attending Veterinarian. Minor medical procedures (such as biological sample collection) may be performed by research staff. Due to the limited number of species involved, the research staff normally requires minimal training prior to commencement of work.

3) Describe the training and experience required to perform anesthesia. [Guide, p. 122]

Only a staff veterinarian, who may be assisted by the Animal Care Specialists, performs anesthesia. The veterinarians are directly supervised by the Attending Veterinarian. Training is obtained from a variety of sources, depending on the individual, and is often a combination of specialized institutional didactic and hands-on

experience, as well as extensive on-the-job training. Refresher equipment training is obtained during routine equipment maintenance.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [Guide, p. 124]

No planned euthanasia as part of a research protocol is performed on marine mammals. Instances of euthanasia would be on a case-by-case basis and for humane reasons only. All euthanasia is conducted by a staff veterinarian only and in accordance with 2013 AVMA Guidelines on Euthanasia. Attending Veterinarian has oversight on all euthanasia procedures.

b. Occupational Health and Safety of Personnel [Guide, pp. 17-23] Describe the institutional entities that are involved in the planning, oversight, and operation of the institutional occupational health and safety program.

The MMP's Occupational Health Program focuses on risks associated with chemical, radiation, physical hazards, zoonoses, injuries from animals, and ergonomic injuries. Enrollment is mandatory for all employees that handle marine mammals or work in the operational area. The Occupational Health Representative tracks enrollment in the program, coordinates medical exams and training, and liaises with the Command Safety and Environmental Office and Radiation Safety Program to ensure regulations are met, hazards are identified, and preventative measures are instituted.

New employees are required to complete a Risk Assessment form and an Occupational Health Exam prior to working with marine mammals, and whenever they have a major change in health status. Annual training on Occupational Hazards is completed during Animal Care Briefs, and sign-in sheets are maintained.

The Command Safety and Environmental Office, Code 83500, administers the SSC Pacific Office of Safety & Health Agency (OSHA) Program. This program covers all safety and health issues as listed in references (a) through (d). Code 83500 provides annual safety inspections of all areas on the center. Additional Industrial Hygiene (IH) support (i.e., formalin vapor exposure monitoring) is provided by Naval Medical Center San Diego. All OSH, IH, IG and Regulatory inspection/abatement/work place survey documentation is maintained in the Safety and Environmental Office, Code 83500, (b)(3) See references:

- a. NOSCINST 5100.5C, 6 August 1990
- b. OPNAVINST 5100.23G, 21 July 2011
- c. SEO SOP No. 2, Lifecycle Management of Hazardous Materials/Wastes
- d. SEO SOP No. 3, Bloodborne Pathogens Exposure Control Program
- e. NRaDINST 5104.1, Radiation Safety Program Manual
- f. SAIC Environmental Compliance & Health and Safety Program
- g. 29 CFR Ch XVII, Subpart T, Commercial diving operations

A Respiratory Protection Program is administered through the Command Safety Office based on IH survey documenting the need for such protection, and where engineering control is not feasible. An SSC Respiratory Protection Program Manager (RPPM) is assigned and responsible for:

- (1) Fit testing and respirator selection
- (2) Annual training
- (3) Standard Operating Procedures
- (4) Evaluation of the RPP

No respiratory protection devices are to be worn at SSC Pacific unless issued by the RPPM.

Hazardous Material/Regulated Medical Waste - All potentially hazardous biological materials are handled and disposed of in accordance with the MMP Clinical Veterinary Services SOP #16, BIOHAZARD WASTE HANDLING AND DISPOSAL. The Animal Care Specialists receive documented hazardous materials handling training and oversee the hazardous materials handling and bio-hazardous waste disposal by veterinary personnel assisted by a designated SSC Pacific point of contact. 10% neutral buffered formalin is prepared and used under a certified fume hood within the pathology laboratory for fixation of tissues harvested at necropsy. Safety Data Sheets (SDS) for all cleaning agents and laboratory reagents used on-site are maintained in the water quality laboratory and the clinical pathology lab. All personnel are reminded to consult the SDS during Animal Care Brief training sessions.

Bloodborne Pathogens Exposure Control Plan is directed by the Command Safety and Environmental Office Code 83500. SSC Pacific's mission and operations provide minimal potential for exposure to infectious material.

Radiation Safety Program is directed by the Command Safety Office. All approved users receive annual documented radiation safety training and the use application is reviewed as needed. The most recent ionizing radiation use application is available for review. Only approved users operate the equipment and all are provided with protective shielding and individual dosimetry monitors.

A Hearing Conservation Program is administered by the Command Safety Office and proper Personal Protective Equipment (PPE) is issued, based on noise survey documentation. The program manager is responsible for:

- (1) Arranging annual audiometric testing
- (2) Proper audio protection selection
- (3) Annual training

There are no specific design features to reduce noise. Animal noise is not a problem. No MMP activities produce noise above safety thresholds.

i. Hazard Identification and Risk Assessment [Guide, pp. 18-19; See also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997]

1) Describe the process used to identify, evaluate and control experimental and other potential hazards (such as ionizing and non-ionizing radiation, chemical cleaning agents, animal bites, allergens, zoonoses, and venomous species) inherent or intrinsic to the use of animals by the institution. Describe how risks of these hazards are assessed and how procedures are developed to manage the risks.

The Occupational Health Representative works with the Command Safety and Environmental Office and NMCSD and Naval Training Center Occupational Health and Safety Office to identify and assess hazards and manage risks. When significant hazards are identified, the Occupational Health Representative consults with the Safety and Environmental Office to mitigate those risks. Training and awareness of hazards is the most important method of risk reduction. The identified hazards are included in the SSC Pacific Biosciences Division Occupational Health and Safety Briefing that every employee receives with their supervisor upon hire. These hazards are regularly reviewed during Animal Care Briefs. Division SOP 34, "Occupational Health and Safety", outlines the program for SSC Pacific MMP

2) Describe procedures for reporting and evaluating exposure to hazards, work place injuries, etc.

Accident and Injury Investigations are conducted by the Command Safety and Environmental Office Code 83500 and required regulatory logs maintained (i.e. OSHA 200 log, Naval Safety Center Reports, etc.) in the Safety Office, (b)(3) Supervisors are required to submit a supervisor's report of injury to Code 83500 to initiate investigation and ensure documentation.

ii. Facilities, Equipment and Monitoring [Guide, pp. 19-20]

1) Describe how hazardous agents are contained within the study environment and in the animal housing area.

Hazardous agents include formalin, anesthetic gases, cleaning chemicals, cold sterilants, (Hydrochloric acid). These agents are not maintained in any animal housing areas. Agents are maintained in Necropsy, chemical storage lockers, spray bottles in VetLab and (b)(3)

2) Describe facilities that use hazardous agents. Note square feet/meters, number of animal rooms, and support spaces. In addition, describe design features, construction features, and special equipment, especially as they relate to hazard containment. Note if, and how, exhaust air is treated. If special facilities are not available and

animals exposed to hazardous agents are housed within conventional animal rooms, so note.

Currently, there are no facilities that utilize hazardous agents in support of a protocol study. All hazardous agents are as described in ii. Facilities, Equipment and Monitoring 1) above and are used in environment cleaning and tissue preservation in non-animal housing areas.

3) Describe the oversight process and husbandry practices in place to ensure personnel safety, including any personal protective equipment provided when work assignment involves hazardous agents.

All research protocols involving hazardous agents conducted or planned at the Center are subject to review and approval by the Command Safety Environmental Office (Code 83500) in addition to review and approval by the IACUC and Senior Scientist for Animal Care and Research.

Personal Protection Equipment (PPE) is supplied by Code 83500 to all SSC-Pacific personnel. Contractors organizations provide additional protective clothing as needed by contract personnel. Protective outer garments (rubberized aprons, butyl gloves, disposable latex gloves, masks and goggles) are available for use as appropriate for the material utilized.

4) Describe any facilities that may also be used for human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

There are no currently approved protocols that would require the administration or exposure of animals to hazardous agents. Past protocols with hazardous agents (radioactive) were administered in human hospitals/clinics.

In past and future protocols that might require the use of human patient areas, prior to each transport, the veterinary staff and animal care and training staff are briefed on specific roles and procedures. The veterinary staff conducts hazard analysis, and develops necessary mitigations to hazards. Dolphins are transported in enclosed beaching mats, which prevent contact with the public. Sea lions are transported in cages to prevent contact with the public. Once the animal arrives at the designated room, only those involved directly with the procedure are allowed access. All SOPs and policies applicable for humans are followed to ensure the same safety standards are met. All excrements are contained on plastic sheeting to protect equipment and future

patients from hazardous wastes. Following procedures, the entire space is thoroughly cleaned by SSC-Pacific and NMCSD personnel.

All above procedures are also practiced for routine, clinical care, diagnostic radiographic procedures conducted at human hospitals.

5) Describe any other circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

The veterinary staff conducts hazard analysis, and develops necessary mitigations to hazards. Dolphins are transported in enclosed beaching mats, which prevent contact with the public. Sea lions are transported in cages to prevent contact with the public. Once the animal arrives at the designated room, only those involved directly with the procedure are allowed access. Transportation is coordinated with hospital staff and transport personnel control animal movement and eliminate contact with individuals not associated with the animal care and use program throughout common use corridors.

The veterin

6) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses.

Only personnel associated with the Navy Marine Mammal Program are authorized to drive during animal transports. These personnel are enrolled in the Occupational Health and Safety Program, and undergo medical evaluation and training prior to employment.

iii. Personnel Training [Guide, p. 20]

1) Describe educational program(s) to inform personnel about zoonoses, personal hygiene, allergies, and other considerations regarding occupational health and safety.

All animal care personnel (federal employees, military, and contract personnel) undergo annual zoonotic disease, sanitation, hygiene, and occupational health and safety training as part of the Animal Care Brief training program.

Contract personnel: Contract management maintains records of individual training and certification programs for all its employees. Training and certification of contract employees is task-driven to cover both general and specific work performed under SSC Pacific's

Biosciences Division. The variety and unique aspects of work performed by contract employees including marine mammal husbandry and training, SCUBA diving, operation of small craft and special vehicles, such as fork lifts, necessitate internally developed and implemented training and certification which go beyond the scope of OSHA specific requirements. Training and certification has been expanded and established to meet the specific nature of the task and the use of special tools and equipment. Current training and certification of contract employees is discussed below.

<u>Diving</u>: Contractor diving programs consist of a Diving Officer who implements policies and procedures, Assistant Diving Officer, Diving Supervisors and individual dive team members. Diving Supervisors are designated in writing by the Diving Officer upon recommendation of the Assistant Diving Officer and after successful completion of a written examination and close observation in supervising a series of diving operations "while under instruction". Prospective dive team members must hold a valid certification through a national recognized open water diving program (i.e., U.S. Navy, NAUI, PADI, SSI, etc) as a prerequisite to enter status as a certified diver. Dive team members complete a written examination and practical skills test prior to contractor certification. Contract dive team members are designated in writing by the Diving Officer upon recommendation of the Assistant Diving Officer or Diving Supervisor.

Small Boat Handling: Contract employees engaged in small boat handling are indoctrinated and internally certified through a "Boat Qualification Course". Course content consists of classroom instruction, practical skills demonstration and written examination in aspects of safe boat handling and boat safety equipment. A certificate is awarded on successful completion of the course. Federal employees and military personnel are required to take the online California Boating Safety course and be licensed as small boat operators. Equivalent courses completed with the US Navy are also recognized.

<u>Forklift Operation</u>: Army and Contract forklift operators at SSC Pacific, Code 715 complete a two hour OSHA compliant "Powered Industrial Forklift Safety Training" course and are issued a certificate and a Letter of Designation for forklift operations at the completion of training. Certification is valid for three years.

2) Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

Radiation Safety Program is directed by the Command Safety Office. All approved users receive annual documented radiation safety training and the use application is reviewed as needed. The most

recent ionizing radiation use application is available for review. Only approved users operate the equipment and all are provided with protective shielding and individual dosimetry monitors. All users must follow safety requirements as outlined in MMP Clinical Veterinary Services SOP #19, MEDICAL DIAGNOSTIC IMAGING. The Occupational Health Representative maintains copies of Radiation Exposure Reports for all veterinary personnel. The previously approved protocols involving hazardous agents were approved through the Radiation Safety Officer (RSO) who maintains primary oversight. Precautions are taken by all personnel to effectively contain materials during transport.

All potentially hazardous biological materials are handled and disposed of in accordance with the MMP Clinical Veterinary Services SOP #16, BIOHAZARD WASTE HANDLING AND DISPOSAL. The Animal Care Specialists receive documented hazardous materials handling training and oversee the hazardous materials handling and bio-hazardous waste disposal by veterinary personnel.

Safety Data Sheets (SDS) for all cleaning agents and laboratory reagents used on-site are maintained in the water quality laboratory and the clinical pathology lab. All personnel are instructed during Animal Care Brief training sessions to consult the MSDS.

iv. Personal Hygiene [Guide, p. 20; Ag Guide pp. 4-5]

1) List routine personal protective equipment and work clothing provided for animal care personnel, technical staff, farm employees, etc. Describe arrangements for laundering work clothing.

Personal Protection Equipment (PPE) is supplied by Code 83500 to all SSC Pacific personnel. Contractors provide additional protective clothing as needed by contract personnel. Protective outer garments (rubberized aprons, butyl gloves, disposable latex gloves, masks and goggles) are available and their use is directed by the necropsy surgeon for all personnel involved in necropsies. All personnel accessing ultra-low freezers wear protective gloves. Rubber gloves and goggles are available and their use is encouraged in animal food container cleaning and sanitizing areas. A hard hat and steel toe footwear are provided and required when operating a forklift or the davit on pier and animal housing locations.

An emergency eyewash and shower station is located on the exterior wall immediately outside the necropsy/pathology room in (b)(3) and eyewash station is located in (b)(3) The emergency eyewash station is flushed weekly.

Laundry facilities for medical linens are provided in (b)(3)
Designated scrubs are used in necropsy. Laundry facilities for all training personnel are present in (b)(3)

2) Describe provisions for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

Four shower/locker room/lavatory facilities are provided for the use of animal care personnel. Separate gender facilities are located in the lower level of (b)(3) and facilities are located in the upper (female facilities) and lower (male facilities) level of (b)(3)

Veterinary personnel also have access to shower facilities in Building 6. Additional lavatory facilities are found in (b)(3)

Hand washing facilities are also located in the (b)(3)

diagnostic treatment facility and in (b)(3)

Shower/locker room/lavatory facilities are located near (b)(3)

Separate gender restrooms are located near (b)(3)

3) Describe policies regarding eating, drinking, and smoking in animal facilities.

In accordance with federal work place policies, smoking is only permitted in designated areas within the center. There are no designated indoor smoking areas. The use of tobacco in any form is not permitted in or around the animal enclosures or treatment facilities at any time. Eating is restricted to administrative spaces. Refrigerators for biological, pharmaceutical, and clinical specimens are clearly labeled as such, as are refrigerators for human food only.

v. Animal Experimentation Involving Hazards [Guide, pp. 20-22]

1) Describe briefly institutional policies governing experimentation with hazardous biological, chemical, and physical agents, including the oversight process for the use of hazardous agents. Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the AAALAC site visit. If such policies and procedures are not available, please explain.

Currently, there are no active research protocols that involve experimentation with hazardous biological, chemical and physical agents.

All potentially hazardous biological materials are handled and disposed of in accordance with the MMP Clinical Veterinary Services SOP #16, BIOHAZARD WASTE HANDLING AND DISPOSAL. The Animal Care Specialists receive documented hazardous materials

handling training and oversee the hazardous materials handling and bio-hazardous waste disposal by veterinary personnel. 10% neutral buffered formalin is prepared and used under a certified fume hood within the pathology laboratory for fixation of tissues harvested at necropsy.

All research protocols involving hazardous agents conducted or planned at the Center are subject to review and approval by the Command Safety Office (Code 83500) in addition to review and approval by the IACUC and Senior Scientist for Animal Care and Research. There are currently two approved animal use protocols involving hazardous agents.

2) Describe aspects of the health and safety program specifically for personnel potentially exposed to hazardous agents.

Currently, there are no active research protocols that involve experimentation with hazardous biological, chemical and physical agents.

In the past, approved protocols involving hazardous radiation agents have been approved through the Radiation Safety Officer (RSO) who maintains primary oversight. Precautions are taken by all personnel to effectively contain materials during transport. There are no changes to housing practices for animals involved with these protocols. Containment of hazardous agents is the responsibility of all participants in the protocol with oversight by the RSO, who is guided by the decisions and approval of the SSC Pacific Radiation Safety Committee.

The Radiation Safety Program is directed by the Command Safety Office. All approved users receive annual documented radiation safety training and the use application is reviewed as needed. The most recent ionizing radiation use application is available for review. Only approved users operate the equipment and all are provided with protective shielding and individual dosimetry monitors.

Hazardous Material/Waste - All potentially hazardous biological materials are handled and disposed of in accordance with the MMP Clinical Veterinary Services SOP #16, BIOHAZARD WASTE HANDLING AND DISPOSAL. The Animal Care Specialists receive documented hazardous materials handling training and oversee the hazardous materials handling and bio-hazardous waste disposal by veterinary personnel. 10% neutral buffered formalin is prepared and used under a certified fume hood within the pathology laboratory for fixation of tissues harvested at necropsy.

Safety Data Sheets (SDS) for all cleaning agents and laboratory reagents used on-site are maintained in the water quality laboratory

and the clinical pathology lab. All personnel are instructed during Animal Care Brief training sessions to consult the MSDS.

There is no requirement for shower and change facilities for animal care personnel, although facilities are available. An emergency eyewash and shower station is located immediately outside necropsy.

Accident and Injury Investigations are conducted by Code 83500 and required regulatory logs are maintained (i.e. OSHA 200 log, Naval Safety Center Reports, etc.) in the Safety Office, (b)(3)

Supervisors are required to submit a supervisor's report of injury to Code 83500 to initiate investigation and ensure documentation.

3) Describe safety procedures for using volatile anesthetics and how waste anesthetic gases are scavenged.

Anesthetic gases, such as sevoflurane, are only used during clinical procedures in (b)(3) and are scavenged via an active diffusion system (Life line Medical System). Industrial Hygiene Department from Naval Medical Center San Diego conducts ventilation surveys and evaluations of waste anesthetic gas periodically to ensure compliance with standards.

- 4) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. Note: This information may be provided as an Appendix.
 - **a)** Biological agents, noting hazard level (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.).

None

b) Chemical agents, noting general category of hazard (toxicant, toxin, irritant, carcinogen, etc.).

None

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

None

5) Describe the program for housing and caring for animals exposed experimentally to the hazardous agents noted above, with emphasis

on management and safety practices for containment of each class of agent. Indicate how levels of personnel exposure are assessed.

N/A

vi. Personal Protection [Guide, pp. 21-22]

1) Describe training, equipment and procedures employed to reduce potential for physical injury, inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

Training: Occupational health hazards inherent to animal facilities and risk mitigation are discussed in annual mandatory Animal Care Briefs. An Animal Handler Course, which addresses hazards unique to the species used, is required for all new employees. New employees are also briefed by their supervisor or the Occupational Health Representative on specific risks associated with their job.

Equipment: Personal Protection Equipment (PPE) is supplied by Code 83500 to all SSC Pacific personnel. Contractors provide additional protective clothing as needed by contract personnel. Protective outer garments (rubberized aprons, butyl gloves, disposable latex gloves, masks and goggles) are available and their use is directed by the necropsy surgeon for all personnel involved in necropsies. All personnel accessing ultra-low freezers wear protective gloves. Rubber gloves and goggles are available and their use is encouraged in animal food container cleaning and sanitizing areas. A hard hat and steel toe footwear is provided and required when operating a forklift or the davit on (b)(3) Laundry facilities for medical linens are provided in (b)(3) Designated scrubs are used in necropsy. Laundry facilities for all training personnel are present in (b)(3)

A Respiratory Protection Program is administered through Code 83500 based on IH survey documenting the need for such protection, and where engineering control is not feasible.

A Hearing Conservation Program is administered by Code 83500 and proper Personal Protective Equipment (PPE) issued, based on noise survey documentation. There are no specific design features to reduce noise. Animal noise is not a problem. No activities produce noise above human safety thresholds.

BUMED and internal inspections address and evaluate safety of physical workplace environment. Annual Occupational Health and Safety Brief addresses ergonomics, physical, chemical and zoonotic disease. VetLab SOP #16 "Hazardous Material Waste Handling and

Disposal" addresses proper sharps and hazardous waste handling disposal.

2) Describe the procedures for the maintenance of protective equipment and how its function is periodically validated.

Chemical respirators are supplied to Army personnel through the Respiratory Protection Program. Maintenance involves negative and positive seal checks, condition of face piece, headband, valves, filters, and cartridges. Inspections are conducted by the Respiratory Protection Program Manager as deemed necessary and should be evaluated by the user prior to use.

X-ray gloves and aprons are checked annually.

3) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc. Describe how such equipment is selected and how respirator fit testing and training in the proper use and maintenance of the respirator is provided.

Respirators are available to military personnel who prepare and mix formalin in enclosed spaces. A Respiratory Protection Program is administered through Code 83500 based on IH survey documenting the need for such protection, and where engineering control is not feasible. A Respiratory Protection Program Manager (RPPM) is assigned and responsible for:

- (1) Fit testing and respirator selection
- (2) Annual training
- (3) Standard Operating Procedures
- (4) Evaluation of the RPP

A fume hood is used in necropsy for transferring large quantities of formalin, trimming tissues and transferring tissue for final archiving.

4) Describe program policies to ensure personnel safety when working with rack/cage washers, other sanitation/sterilization equipment, and other heavy equipment such as scrapers, tractors, and farm machinery. Describe the training program that supports these policies.

Small Boat Handling: Contract employees engaged in small boat handling are indoctrinated and internally certified through a "Boat Qualification Course." Course content consists of classroom instruction, practical skills demonstration and a written examination covering aspects of safe boat handling and boat safety equipment. A certificate is awarded upon successful completion of the course. Federal employees and military personnel are required to take the online California Boating Safety course and be licensed as small boat

operators. Equivalent courses completed with the US Navy are also recognized.

<u>Forklift Operation</u>: Army and contract forklift operators at SSC Pacific, Code 715 complete a two hour OSHA compliant "Powered Industrial Forklift Safety Training" course and are issued a certificate and a Letter of Designation for forklift operations at the completion of training. Certification is valid for three years.

vii. Medical Evaluation and Preventive Medicine for Personnel [Guide, pp. 22-23]

1) Identify the individual(s) and/or office responsible for developing and monitoring the medical evaluation and preventive medicine program.

The Occupational Health Representative is responsible for monitoring the medical evaluation program. The position is currently held by an Army veterinariary corps officer.

2) Describe the categories of personnel (research staff, visiting scientists, animal care staff, students, support staff, etc.) included in the program.

Personnel that work directly with marine mammals, or regularly perform work in the animal care and holding facilities, are required to enroll in the program. This includes all veterinarians and animal care staff, research staff, animal trainers and supervisors, interns, and IACUC members.

3) Describe general features of the medical evaluation and preventive medicine programs, including pre-employment/pre-assignment health evaluation, periodic medical evaluations, immunization programs, and procedures for communicating health related issues.

All employees are provided a copy of the Occupational Health Risk Assessment, which identifies the specific hazards they are exposed to. All employees are required to complete the form and schedule an Occupational Health exam to ensure vaccinations are current and that no significant health problems exist, which may limit their ability to work. Federal and military employees are required to schedule their Occupational health exam or risk assessment through the Naval Training Center's Occupational Health department. All contract employees must schedule their own exam, but are provided with a physician's guide identifying specific risks associated with working with marine mammals. Employees are encouraged to periodically repeat the exam, but are only required to do so in the event of a major health status change. A copy of the completed Occupational Health

Risk Assessment, signed by the employee's doctor, is maintained by the Occupational Health Representative.

All personnel involved in animal care and training dive operations undergo an OSHA directed annual diving physical examination performed by the contractor's medical services. Medical records including the physician's report and approval form are maintained by contract management.

Tetanus vaccination is recommended for Marine Mammal Program personnel and provided on a voluntary basis.

TB testing is provided annually for military.

4) Describe special precautions or procedures for personnel exposed to potentially hazardous species (nonhuman primates, sheep, etc.) or agents (infectious agents, human origin tissues, chemicals/toxins, etc.).

Hazardous Material/Waste - 10% neutral buffered formalin is prepared and used under a certified fume hood within the pathology laboratory for fixation of tissues harvested at necropsy. All potentially hazardous biological materials are handled and disposed of in accordance with the MMP Clinical Veterinary Services SOP #16, BIOHAZARD WASTE HANDLING AND DISPOSAL. The Animal Care Specialists receive documented hazardous materials handling training and oversee the hazardous materials handling and biohazardous waste disposal by veterinary personnel. Bloodborne Pathogens Exposure Control Plan is directed by the Command Safety and Environmental Office Code 83500. SSC Pacific's mission and operations provide minimal potential for exposure to infectious material.

c. Investigating and Reporting Animal Welfare Concerns [Guide, pp. 23-24] Describe institutional methods for reporting and investigating animal welfare concerns.

Animal welfare concerns are addressed in the IACUC SOP 06-11 "Investigating Potential Animal Care and Use Concerns." Instructions for reporting animal welfare concerns are posted throughout the facility in prominent locations. Included in the instructions are several points of contact as well as the whistleblower policy. Reporting procedures are covered at least annually as part of the mandatory Animal Care Briefs. Anyone can report potential animal care and use concerns directly to any IACUC member including the Administrator, the AV, and any institution official, this includes the ASRC as well as anonymously to the SSC Pacific IG. Once a report is received by the IO, AV, or member of the IACUC, per SOP, the Chair and AV are notified and meet to review the complaint. If a complaint requires further investigation, the Chair or their designee, perform a complete investigation.

All members of the IACUC, the IO, and BUMED are informed of the findings. If a research activity is suspended, it is reported to APHIS and AAALAC and any federal agency funding that activity.

B. Program Oversight

- 1. The Role of the IACUC/OB [Guide, pp. 24-40]
 - **a.** IACUC/OB Composition and Function [Guide, pp. 17; 24-25] Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as an appendix.
 - i. Describe Committee membership appointment procedures.

The MMP IACUC membership is appointed by Mr. Mike Rothe, Director, Navy Marine Mammal Program, who serves as the Institutional Official. The committee, as set forth in SECNAVINST 3900.41G, and NRaD code 51 memo Ser 51/35-94, is appointed by the Director, Navy Marine Mammal Program, by direction of the SSC Pacific Commanding Officer. Consultants to the committee participate under invitation of the Chair. The IACUC is composed entirely of Federal employees, with ten members currently appointed, in accordance with the Animal Welfare Act and DoD Instruction 3216.01. This includes, but is not limited to an attending veterinarian, a practicing scientist, a member from a nonscientific background, and a member not affiliated with the program or animal research. The function of the IACUC is to oversee the care and use of marine mammals and to facilitate regular protocol and program reviews and facility inspections.

ii. Describe frequency of Committee meetings.

The IACUC meets at least twice annually (not more than six months apart) to review all current protocols, perform a program review and facility inspection in accordance with Title 9 CFR, Chapter 1, Subchapter A. Facilities inspections and program reviews employ DoD Semiannual Program Review/Facility Inspection Forms and Checklists. Completed meeting minutes, forms, and checklists are sent to the Director, Navy Marine Mammal Program, for signatory approval "by direction" of the Commanding Officer. After approval the minutes are distributed to SSC Pacific Codes 71000, 71500, 71530, 71510, 71502, and Committee membership.. A copy of the last review report is available upon request.

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [Guide, p. 17]

All new IACUC members receive comprehensive training on the MMP's animal care and use program, including roles and responsibilities of IACUC members. All IACUC members also receive refresher training on

rotating animal care and use topics at every semiannual facilities and program review. Training includes initial orientation to the program, duties and responsibilities of the IACUC, protocol review, ethics of animal use, program review, facilities inspection and regulatory requirements.

b. Protocol Review [Guide, pp. 25-26]

A blank copy of your institution's protocol review form should be provided as an appendix. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal study protocols, including research and teaching proposals. Include a description of how animal study protocols that do not involve a formal grant proposal are reviewed and approved (i.e., pilot studies or internally funded studies). Include a description of how the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the research. Describe how protocols that have the potential to cause pain or distress to animals are reviewed, alternative methodologies reviewed, veterinary input solicited, and studies controlled or overseen. Specify how animals and experimental group sizes are justified.

The PI submits a protocol in accordance with SECNAVINST 3900.38C Appendix C DOD Animal Use Protocol Format (16 February 2005). A black copy of the protocol template is available for review in Appendix 7. This format includes comprehensive replacement, refinement and reduction of animal use statements. The cover sheet includes verification signatures ensuring appropriate scientific review, attending and consulting veterinary review, and appropriate statistical review. All requests for review of animal use protocol proposals are first submitted to the Administrator for preliminary review (formatting and omission errors). The protocol is then distributed for scientific, veterinary and statistical review. Once the scientific, veterinary and statistical reviews are complete, the Administrator disseminates the full protocol to the IACUC electronically for their review. The IACUC is provided a set number of working days to review the protocol and report to the Administrator on whether they support moving forward on the protocol with a designated review, or request a full committee review. Approved protocols are then submitted to the Naval Bureau of Medicine and Surgery (BUMED) for their review and concurrence of approval. All animal research, regardless of funding source, requires IACUC review and approval. All protocols are reviewed at each semi-annual meeting.

The IACUC is especially aware of the unique nature of the research population and the high value of the animals, therefore all research proposals are meticulously scrutinized to ensure the potential benefits outweigh the potential adverse effects. The committee includes animal trainer supervisors who are especially attuned to the unique characteristics and needs of the animals. Before any protocol is considered, the PI must consult with the Senior Scientist regarding the scientific credibility of the

research, a statistician to justify animal group size, and the Attending Veterinarian to ensure any procedure causing pain or distress is justified, properly mitigated, and alternative methodologies are considered. Once approved, the Senior Scientist and Attending Veterinarian supervise all projects to ensure compliance with the approved protocol.

ii. Describe process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description of "major" vs. "minor" amendments.

If a PI desires to amend a protocol, they must submit a memorandum to the Chair describing the requested amendment with justification. Minor amendments are considered by the Chair and Attending Veterinarian via designated review. Major amendments are distributed to the committee and follow the same procedures as described above for approving protocols.

Major amendments are described as a change in overall objective of study, a change resulting in a different USDA category, a change in anesthetic agents or use, change from non-surgery to surgery or minor to major surgery, change in species, addition of hazardous agents, a change in PI, or an increase in number of animals greater than 10%.

Minor amendments are described as an increase in animal numbers less than 10%, a change in technique that does not change the intent or the protocol or result in change of USDA category, change in dose or route of administration of a drug, change in frequency or duration of procedure, changing protocol support personnel.

Once amendments are approved by the IACUC, the protocols are submitted to the Naval Bureau of Medicine and Surgery (BUMED) for their review and concurrence of approval.

- c. Special Considerations for IACUC/OB Review [Guide, pp. 5; 27-33]
 - i. Experimental and Humane Endpoints [Guide, pp. 27-28] Describe how criteria for determining alternatives to experimental (humane) endpoints are developed, approved, and applied. Include a description of monitoring systems in place for studies for which information on alternative endpoints are not available.

Protocols are reviewed by the IACUC every six months during the semiannual IACUC meeting. At that time the IACUC is updated on the progress of each study. The experimental endpoint goal is clearly outlined in each protocol. Criteria for early endpoints include weight loss, decreased appetite, or clinical illness and are at the discretion of the Attending Veterinarian. Regular communications occur through the AV with the rest of the IACUC if these criteria develop. Due to the unique

nature of the animal population being studied, no research is performed that results in the potential for unrelieved or severe pain and distress. Research protocols on the navy marine mammals are minimally invasive and do not involve major surgery, euthanasia, or death.

ii. Unexpected Outcomes that Affect Animal Well-being [Guide, pp. 28-29]

Describe how unexpected outcomes of experimental procedures (e.g., unanticipated phenotypes in Genetically Modified Animals) are identified, interpreted, and reported to the IACUC/OB.

All animals on protocols are closely observed (daily assessments performed) and unexpected events are reported to the IACUC and AV with determination of cause and resolution.

iii. Physical Restraint [Guide, pp. 29-30]

Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices.

Research protocols involving the Navy Marine Mammals do not involve prolonged restraint.

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe the duration of confinement, acclimation procedures, monitoring procedures, criteria for removing animals that do not adapt or acclimate, and provision of veterinary care for animals with adverse clinical consequences.

None

iv. Multiple Survival Surgical Procedures [Guide, p. 30]

Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the institutional policy(ies) regarding multiple survival surgery (major or minor) on a single animal.

The MMP does not have research protocols involving multiple major surgeries.

2) Describe the procedure for approving multiple survival surgery (major or minor) and the criteria used to determine the potential impact on the animals' well-being.

Multiple surgeries would occur as standard of care only.

3) Summarize the protocols currently approved that involve multiple major survival surgical procedures and the time allowed between procedures on the same animal. Describe the method of institutional monitoring.

There are no current protocols involving multiple major survival procedures.

v. Food and Fluid Regulation [Guide, pp. 30-31]

1) Describe experimental situations that require food and/or fluid regulation. Note: This does not include pre-surgical fast. List title of the experiment(s), justification, species involved, and length and type of food/fluid regulation.

None

2) Describe animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumed).

N/A

3) Describe methods of ensuring adequate nutrition and hydration during the regulated period.

N/A

vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [Guide, p. 31]

Describe the rationale and consideration given by the IACUC/OB for use of non-pharmaceutical grade drugs or other substances, if applicable.

The MMP does not have research protocols involving these substances.

vii. Field Investigations [Guide, p. 32]

Describe special considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

The MMP does not currently have research protocols involving field investigations.

viii. Agricultural Animals [Guide, pp. 32-33]

Describe considerations given and guiding documents used by the IACUC/OB when reviewing "biomedical" and "agricultural" research projects involving agricultural species as study animals, if applicable.

The MMP does not have research protocols involving agricultural animals.

ix. Animal Reuse [Guide, p. 5]

Describe institutional policies and/or oversight of animal reuse (i.e., on multiple teaching or research protocols). Summarize the protocols currently approved that involve the reuse of individual animals.

Due to the unique population and goals of the research program, animal reuse for research protocols are common. Most research protocols are non-invasive and are used to advance and improve the knowledge, methods, and equipment for navy marine mammal veterinary care, and to monitor the impact of human activities on marine mammals. The IACUC closely scrutinizes each protocol to ensure that individual animals are not involved in too many research programs at one time. Twelve animals are currently on multiple protocols, however, protocols are minimally invasive and multiple use is not considered to impact the animals.

2. Post-Approval Monitoring [Guide, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic reviews (e.g., annual review, 3-year renewals if PHS funded, etc.).

All protocols are reviewed every six months during the semi-annual IACUC meeting. IACUC members are provided updates on the progress of each study.

The Attending Veterinarian or veterinary staff regularly observe procedures, and directly support any procedure requiring anesthesia or other medical procedures. Animals are observed daily by veterinary and animal care staff and IACUC members. The IACUC Administrator and chair receives an update on the activities under each protocol at monthly Research Meetings and the Attending Veterinarian and IACUC Chair receive updates on protocols at weekly VetLab meetings.

b. Describe the process and frequency with which the Committee reviews the animal care and use program and conducts facility and laboratory inspections. Detail any criteria used for exempting or varying the frequency of reviewing satellite holding facilities and animal use areas. If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities. Note: A copy of the last report of these reviews should be included as an appendix.

A copy of the last two semiannual IACUC program review and facility inspections are included in Appendix 9. The committee meets at least twice

annually (not more than six months apart) to review all aspects of animal care and to ensure that the facility and programs are in compliance with all policies, standards and regulations. The committee also inspects all animal housing and care facilities semiannually in accordance with Title 9 CFR, Chapter 1, Subchapter A. Facilities inspections and program reviews employ DoD Semiannual Program Review/Facility Inspection Forms and Checklists. No contract facilities are in use.

c. Describe institutional responses to deficiencies noted on regulatory inspection reports (e.g., government, regulatory agencies). Note: Copies of all such inspection reports for the past three years (if available) should be available for review by the site visitors.

The MMP provides a followup to correct deficiencies and provides a written response to all external inspection reports of deficiencies.

All internal deficiencies identified are included in the semiannual report to the IO. A worksheet distinguishes significant and minor deficiencies, the location of the deficiency, a plan for correcting the deficiency, the party responsible for correcting the deficiency, a schedule for correcting the deficiency, and a date the deficiency was corrected. The IACUC chair/administrator continues to follow up on all outstanding minor deficiencies on a monthly basis until all deficiencies are corrected.

All regulatory inspection reports are kept on file by the Chief of US Army Element. Reports are distributed to the IO and IACUC for review. The IO, Chair, and IACUC work to contact the responsible party and ensure all deficiencies are addressed.

d. Describe other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and regulatory compliance.

The IACUC Administrator receives an update on the activities under each protocol at weekly Research Meetings and the Attending Veterinarian and IACUC Chair receive updates on protocols at weekly Vet Lab meetings.

The Biosciences Division Head has established an Animal Safety Committee (ASC). The purpose of the ASC is to review changes to hardware, methodologies and applications of training employed with working animals to determine if the safest hardware and equipment designs and methodologies practical are being employed. In particular, new hardware and applications are reviewed prior to implementation and existing hardware to be utilized in new areas or greatly expanded in applications, such as transfer from use at SSC Pacific to the fleet systems are reviewed. This committee also reviews accidents involving animals. The committee Chair reports directly to the Division Head.

II. Animal Environment, Housing and Management

Note: Complete each section including where applicable, procedures performed in farm settings, field studies and aquatic environments, etc.

A. Animal Environment

1. Temperature and Humidity [Guide, pp. 43-45]

a. Describe briefly the heating and air conditioning system performance. Provide method and frequency for assessing, monitoring, and documenting animal room or housing area temperature and humidity that is appropriate for each species. Note current (measured within the last 12 months), detailed (by room) performance data are to be provided as indicated on the enclosed Heating, Ventilation, and Air Conditioning (HVAC) System Summary appendix. If outdoor housing areas are used, so note.

Animals are typically housed in outdoor enclosures, using open marine water systems. The animal species used in the MMP are native to the area, so are well suited and acclimated to the ambient temperature and humidity. (b)(3) (procedure room) (b)(3) (surgery suite) of(b)(3) are the only areas that animals may be located temporarily during diagnostic procedures or treatment. (b)(3) has a dedicated auxiliary HVAC unit to maintain temperature conditions required by marine mammals out of the water.

b. If temperature set points and/or environmental conditions are outside the thermoneutral zone for the species, describe the process for ensuring behavioral thermoregulation (e.g., nesting material, shelter, etc.) and/or IACUC/OB approved exception.

Both dolphins and sea lions are native to southern California, and as they are housed in outdoor enclosures, are particularly suited to endure the natural environmental conditions. Sea lions are provided access to water at all times, unless approved by the Attending Veterinarian for medical purposes. During animal transports, animals are kept wet and frequent environmental temperatures are monitored and recorded. Air conditioning units are utilized to regulate temperatures on prolonged transports.

During procedures, animals are continuously monitored for body temperature. In addition to the HVAC system, the veterinary and animal care staffs use several other methods to maintain appropriate body temperature including constant spraying with water, Bair huggers, and heating devices, etc.

2. Ventilation and Air Quality [Guide, pp. 45-47]

a. Briefly describe the performance aspects of the ventilation system. Provide method and frequency for assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with adjacent areas). Note: current (measured within the last 12 months) detailed (by room) information is to be provided as indicated on the enclosed Heating, Ventilation, and Air Conditioning (HVAC) System Summary appendix.

Animals are typically housed in outdoor enclosures. (b)(3) (procedure room) (b)(3) (surgery suite) of (b)(3) are the only areas that animals may be located temporarily during diagnostic procedures or treatment. (b)(3) has a dedicated auxiliary HVAC unit to maintain temperature and positive pressure ventilation conditions required by marine mammals out of the water and during a surgical procedure.

b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

Vetlab (b)(3) surgical suite has an HVAC unit which provides positive pressure ventilation for surgical procedures.

c. If any supply air used in a room or primary enclosure is <u>recycled</u>, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

N/A

3. Life Support Systems for Aquatic Species [Guide, pp. 84-87]

Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics). Describe overall system design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness. Please note that facility-specific tank design and parameter monitoring frequencies should be summarized in the Aquatic Systems Summary appendix.

All dolphins are housed in open-ocean floating net enclosures. The enclosures measure 30' x 30' outside dimensions and are composed of a trex/wood deck/walkway supported by custom fiberglass floats or EZ Dock sections. The floating structure supports a 6" mesh net made of #48 nylon twine. The vertical dimension of the side net is 8'. Net stretch creates an effective maximum vertical dimension of >12'. This arrangement ensures constant socializing via visual and acoustic contact with adjacent animals and interaction with the ocean environs. There are passive mechanical gates that can be opened to allow animals free access to adjoining enclosures or separation for husbandry, training or medical purposes interconnect enclosures. The area underneath the deck/walkways or overhead nylon sunscreens provides protection from sun. The enclosure complexes are dynamic and can be modified to meet social and training requirements. 30' x 60' and 40' x 80' community areas are provided for every four dolphin enclosures.

Sea lions are housed in floating complexes composed of a 15'x 24'x 8' suspended 4" mesh #48 nylon twine anti-fouling net swimming area and 475 ft² of deck dry haul out area. Six individual 24 ft² housing areas for animal separation adjoin the haul out area. TenserTM polygaurd 2" mesh plastic fencing surrounds the entire complex and a sunscreen is affixed over the haul out/individual housing areas. Individual housing dividers and gates are polyvinyl coated chainlink. All metal components

are hot-dipped galvanized or brass galvanized. Conventional marine chain and fender assemblies secure all enclosure complexes to causeways and piers.

An elevator platform, measuring 12' x 30', is located in one of the 30' x 60' enclosures for dolphins. The purpose of this platform is for medical treatment of animals when necessary and early hands-on handling of young animals.

Animals requiring hands-on medical attention that do not perform learned husbandry behaviors (e.g., beaching onto tray) are attended to by lifting enclosure nets. This allows personnel to enter enclosures while standing and manually guide animals into stretchers.

Enclosure systems for all animals use an open system with the bay water, and the veterinary staff performs quality assurance testing to ensure water meets standards. Weekly coliform counts are conducted on bay water at various areas around the pens and in the operational area. Fresh water samples are collected quarterly for heavy metal, pesticide, and hydrocarbon testing.

4. Noise and Vibration [Guide, pp. 49-50]

Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

There are no specific design features to reduce noise or vibrations. DOD operations occurring within the vicinity of the animals are reviewed prior to execution to assure that any noise generated by the operations will not exceed marine mammal safety criteria for noise.

B. Animal Housing (All terrestrial, flighted, and aquatic species)

1. Primary Enclosures

Provide a description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) in appendix.

a. Describe considerations, performance criteria and guiding documents (e.g. <u>Guide</u>, <u>Ag Guide</u>, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

All facility marine mammal enclosures are designed to exceed the standards set forth in 9 CFR Ch.1 (1-1-11 Edition), Subchapter A, Part 3, Subpart E, Specifications for the Humane Handling, Care, Treatment, and Transportation of Marine Mammals, and promulgated by the USDA APHIS.

b. Describe space <u>exceptions</u> to the guiding documents (<u>Guide</u>, <u>Ag Guide</u>, ETS 123, and/or applicable standards), indicating the references, considerations and

performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [Guide, pp. 55-63]

Dolphins are occasionally confined to Animal Transport Containers (ATC's) in accordance with Division SOP #21 TRANSPORTING NAVY CETACEANS. This method has been successfully used by the Navy to transport cetaceans for over 40 years. Under the direct supervision of a veterinarian, in accordance with the above standards, dolphins may be temporarily housed in portable pools for training or medical purposes. Each animal requiring temporary housing in a pool or transport container undergoes an individualized acclimation program for conditioning. The length and program schedule varies with the animal and is dictated by assessments by the senior training staff and veterinarians. Extensive MMP experience has shown that the program is highly successful with no adverse effects on military relevant or husbandry behaviors or medical problems resulting.

2. Environmental Enrichment, Social and Behavioral Management [Guide, pp. 52-55; 63: Ag Guide, Chapter 4]

a. Enrichment

i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g. resting boards, privacy areas, shelves/perches, swings, hammocks, etc.).

The natural ocean enclosure location and arrangement ensures constant visual and acoustic contact with adjacent animals and interaction with the ocean environs. Passive mechanical gates can be opened to allow animals free access to adjoining enclosures and individuals.

ii. Describe nonstructural provisions to encourage animals to exhibit species-typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

All animals receive sessions, as much as possibly each weekday, untethered in the open ocean. Most fleet support animals often accompany their trainers on open ocean sessions. Animals are frequently observed interacting with local indigenous marine fishes and invertebrates and occasionally with nearby marine mammals.

When not interacting with training personnel, animals freely interact with each other and the ocean environment in compatible social groups. A variety of objects (rubber boat bumpers, rub-ropes, etc.) are placed within animal enclosures for environmental enrichment. Additional enrichment devices and programs are under continuous development.

b. Social Environment [Guide, p. 64]

i. Describe institutional policy or strategy for social housing of social species.

As dolphins and sea lions are extremely social animals, all efforts are focused in providing a rich, natural social environment. When not actively engaged in training or working, all animals are housed with at least one other animal. In some cases, animals may be housed separately as approved by the Attending Veterinarian for medical purposes. When physically separated, animals still maintain visual and acoustic communication with other animals. The animal care staff closely monitors the social interactions, such that compatible animals can be housed together and incompatible animals moved to another social grouping.

ii. If social animals are not socially housed, provide justification, as approved by the IACUC/OB.

Animals are only housed separately for medical reasons directed by the Attending Veterinarian. In the case that an animal needs to be separated for medical reasons not involving physical isolation or quarantine, animals are still able to communicate and interact with other animals through enclosure nets in the ocean pens.

iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (e.g., interaction with humans, environmental enrichment, etc.).

When physically separated, animals still maintain visual and acoustic communication with other animals. Animal care staff provide frequent interaction and environmental enrichment.

c. Procedural Habituation and Training of Animals [Guide, pp. 64-65] Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

All animals are trained for routine husbandry procedures, including medical procedures such as phlebotomy, ultrasound exam, endoscopy, gastric tube placement, blowhole swabs, fluid therapy, fecal collection, rectal temperature, full body exams. These behaviors are reinforced daily to reduce or eliminate physical restraint techniques. Before any new technique, such as for research purpose, animals are gradually acclimated to the technique to reduce stress.

d. Enrichment, Social and Behavioral Management Program Review [Guide, pp. 58, 69]

Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

The Attending Veterinarian regularly reviews all cases in which animals need to be socially isolated for medical purposes.

e. Sheltered or Outdoor Housing [Guide, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

All animals are housed in natural, open ocean floating net enclosure in the San Diego Bay. Dolphins are housed in open-ocean floating net enclosures, as described above. Sea lions are housed in floating complexes as described above. The nets used for the swimming area of the sea lion enclosures and the dolphin enclosures allow adequate natural circulation of seawater as the tide shifts.

ii. Describe methods used to protect animals from weather extremes, predators, and escape (e.g., windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

There are passive mechanical gates that can be opened to allow animals free access to adjoining enclosures or separation for husbandry, training or medical purposes interconnect enclosures. The area underneath the deck/walkways or overhead nylon sunscreens provides protection from sun. TenseTM polygaurd 2" mesh plastic fencing surrounds the entire sea lion complex and a sunscreen is affixed over the haul out/individual housing areas.

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

All animals are fed individual rations; therefore competition for food is non-existent. Animal care staff assess behavior and compatibility on a daily basis, and animals are housed with other animals to best suit their compatibility. Passive mechanical gates that interconnect enclosures can be opened to allow animals free access to adjoining enclosures or separation for husbandry, training or medical purposes.

f. Naturalistic Environments [Guide, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being.

Working animals train in open-ocean environments where control is limited. However, this type of natural exposure is restricted to a few hours a day and animal activity is continuously monitored.

ii. Describe how food, water, and shelter are provided.
Working animals are hand fed individual rations when working in open ocean environment.

iii. Describe how animals are captured.

All open water training is conducted under the assumption that trained animals will voluntarily return to the watercraft when instructed. On the rare occasion that an animal will not return, the animal training staff remains in the area and maintains visual contact until the animal returns to the boat or to the housing area.

C. Animal Facility Management

1. Husbandry

- **a. Food** [Guide, pp. 65-67]
 - i. List type and source of food stuffs.

All Navy marine mammals are fed a diet of fish, fresh frozen and restaurant quality (human food grade). A variety of species are fed including but not limited to: capelin (*Mallotus villosus*), herring (*Culpidae spp*), mackerel (*Scromber spp*) squid, (*Loligo spp*), croaker (Genyonemus lineatus), finger mullet (Mugil cephalus) and pinfish (*Lagadon rhomboids*). Fish and squid are purchased from commercial fishing vendors worldwide.

ii. Describe storage facilities of vendors, noting temperature and vermin control measures. If more than one source, describe each.

An initial sanitary inspection of all potential vendors is completed by or under the direction of an US Army veterinarian. The inspection is based on MIL STD 3006C, Appendix A and H, SANITARY INSPECTION OF SEAFOOD PROCESSING FACILITIES, and Fish and Fisheries Products Hazards and Controls Guidelines (2001) and includes specific attention to time/temperature controls and vermin control. Follow-up inspections are performed seasonally during production of species to be supplied as time, personnel, budget and fishery inspection history dictates. Separate

vendors are required for each species of fish, including capelin, herring, mackerel, finger mullet, and squid for example. Product testing is also performed prior to feeding, to include microbial, histamine, biogenic amines, heavy metals, proximate analysis, and other nutritional components.

iii. Describe bulk food storage facilities, if applicable, noting temperature and vermin control measures. Note food storage areas within the specific animal facilities are described below in Section IV.B.4.a. Physical Plant.

Fish is stored frozen at less than 0 degrees Fahrenheit at contracted storage facilities in San Diego. Capelin is stored for up to 18 months; other species are kept for up to a year. Working stocks are delivered from this facility, using first in first out, via refrigerated trucks to two on-site freezers every three weeks. All freezers maintain temperatures less than 0 degrees Fahrenheit. Procurement, delivery, food safety, and inventory control is assured by a civil service employee and the US Army element..

iv. Describe food storage in animal rooms.

Daily animal rations are thawed in stainless steel sinks in fish preparation houses. Thawed fish are layered on ice in insulated plastic coolers and fish are fed within 12 hours throughout the training day. At no time are feed fish allowed to reach a temperature of over 40 degrees Fahrenheit. Freezer, sink, and fish bucket temps are monitored and recorded.

v. Describe food preparation areas.

Each fish preparation area is equipped with multiple banks of stainless steel sinks for fish thawing and final handling prior to bucketing, digital and analog scales, ice machines, and bucket racks for sanitary storage. The fish houses' design follows that of restaurant food service sanitation principles, and meets or exceeds MILSTD 3006C.

vi. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Every animal is provided a customized ration. Ration formulation is done with consideration of the animal's target working weight, morphometric data, caloric content of each fish lot, and consultation of the animal's trainer and attending veterinarian. To approximate a free ranging diet and avoid possible nutritional imbalances, a variety of species is included in each ration. Vitamin and mineral supplements are provided to correct for potential effects of temporal and preparation limitations, and empirical marine mammal requirements. A custom ration formulation spreadsheet has been developed and is used by animal care personnel to promote these practices and enhance future formulation decisions. Each animal's custom ration is hand fed by the animal's trainer as an integral part of the training

day. All training personnel have received documented training on feed fish handling and sanitation procedures. Fish that has contacted a non-sanitized surface or appears unwholesome is weighed and disposed of at the end of the training day IAW Division SOP#6, PROCEDURE FOR ANIMAL FOOD HANDLING.

vii. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio-load, chemical contaminants, etc.

Food stored in the fish house freezers are inspected monthly by veterinary staff, noting expiration dates and storage quality. Fish is thawed using first-in first-out procedures. All fish procurement, processing, transport, storage, and handling are performed IAW the U.S. Navy MMP HACCP (Hazard Analysis and Critical Control Point) plan. Critical control points and potential significant hazards are identified and corrective action taken when monitoring reveals a deficiency. Microbiologic testing is conducted on food contact surfaces monthly. Each lot of fish is subject to organoleptic sensory evaluation and chemical proximate analyses upon procurement as described above.

b. Drinking Water [Guide, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams, etc.).

Healthy dolphins and sea lions typically receive their daily water requirements from fish. Sea lions have access to fresh water at all times in tubs positioned in the haul out areas of the enclosure. These tubs are cleaned and refilled daily. They are occasionally provided ice cubes to eat in the course of a training day. Dolphins may occasionally be provided fresh bottled drinking water or trained to swallow ice cubes for medical purposes.

ii. Describe methods of quality control, including monitoring for contaminants.

The fresh water sources are supplied by the municipal system or commercial drinking water vendors and are not further treated or monitored. Water sources in the fish houses including ice machines and drinking water dispensers receive an annual water potability test.

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

N/A

c. Bedding and Nesting Materials [Guide, pp. 68-69]

i. Describe type(s) and how used for various species.

All animals are housed in open-ocean enclosures; no bedding is employed.

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures. Note bedding storage areas within the specific animal facilities are described below in Section IV.B.4.a.

There are no bedding storage facilities.

iii. Describe quality control procedures, including monitoring for contaminants.

In accordance with Title 9 CFR, Chapter 1, Subchapter A, Part 3, Subpart E, water samples are collected from all piers with animal enclosures and submitted for total coliform determination on a weekly basis. Trained Animal Care Specialists perform microbiologic analysis. All records are archived to a database for future scrutiny and results above action levels are reported to the the Army Veterinarian, on-call veterinarian, and attending veterinarian immediately. In the event action levels are exceeded, follow up sampling and corrective action is conducted in accordance with the Animal Welfare Act and SSC Pacific emergency plan (Division SOP #24, MARINE MAMMAL CONTINGENCY PLAN for SAN DIEGO BAY DISASTER MARINE MAMMAL EVACUATION CONTINGENCY PLAN). Water in closed or semi-closed pool systems is routinely monitored for compliance with microbial limit and chemistry standards. Comprehensive organic, heavy metal, and contaminant chemical analyses are performed as needed to support concept and system development.

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

Sea lions are transported in cages in open backed government vehicles or in the back of an air-conditioned leased panel truck. A handler accompanies sea lions at all times. Sea lions may be moved within "transport" cages or unconfined aboard small boats. Dolphins are transported long distances in Animal Transport Containers (ATC's) in accordance with Division SOP #21, TRANSPORTING NAVY CETACEANS. Short term over-water transports of dolphins are routinely conducted in "beaching trays" as part of open water training or work activities. While aboard small boats, dolphins are moved inside the padded trays, which provide shielding from the sunlight, and access for

keeping the animal cool and wet. For longer transport, cetaceans are transported in ATC's in the back of trucks and in various military aircraft. They are accompanied by a veterinarian and attended to by animal handlers at all times. An ATC consists of a custom fitted, synthetic, fleece lined stretcher with openings for the animal's pectoral flippers and contoured to the flukes, suspended by aluminum poles in brackets which are mounted on a 128" x 32" x 30" (inside dimensions) fiberglass container on pneumatic wheels. The container is filled with water at a level to keep the animal comfortable. Additional fresh water is provided by hand held sprayers to keep the animals wet and cool.

ii. Describe other animal care related equipment used in the animal care program (e.g., specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

Sea Lions may be restrained momentarily for blood collection or close inspection in a Sea Lion squeeze cage on an as needed basis for clinical evaluations. A variety of objects (rubber boat bumpers, rub-ropes, etc.) are placed within animal enclosures for environmental enrichment. Several high-pressure, hot fresh water sprayers are used to clean and defoul these objects. Diagnostic equipment not previously mentioned includes a Pentax® Image Management System for digitized management of diagnostic images. This system supports six fiber optic endoscopes of various configurations and two video endoscopes. A GE Voluson-I ultrasound with a variable transducer from 2.5 - 7.5 MHz, doppler capability, and an endoscope guided ultrasound transducer provides diagnostic sonography images. Three Micromaxx and one Sonosite® 180 diagnostic ultrasound units including two 3.5 MHz and two 5.0 MHz transducers provide sonography capability at remote sites. They are each supported by a visor mounted video signal receiver, and a dedicated digital video recorder. Digital radiography equipment includes Eklin Image management system (RapidStore), EDR5 digital radiology system, Poskom and GE AMX-4 radiology tubes Minxray 4F120/60HPPWV and VetRocket. Anesthetic equipment includes Mallard and NarkoMed anesthesia systems with Sevoflurane vaporizers, GE DASH 4000 and physiological monitoring equipment. Numerous 1" x 4' x 8' high density foam treatment pads, hanging and platform scales, and hand held animal sprayers are in routine use.

e. Sanitation [Guide, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

N/A

2) Describe any IACUC/OB-approved <u>exceptions</u> to frequencies recommended in the <u>Guide</u> or applicable regulations and the criteria used to justify those exceptions.

N/A

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

N/A

- ii. Cleaning and Disinfection of the Micro- and Macro-Environments
 Describe the washing/sanitizing frequency, and methods used in the
 Appendix, "Cleaning and Disinfection of the Micro- and MacroEnvironment."
 - 1) Describe any IACUC/OB-approved <u>exceptions</u> to the <u>Guide</u> (or applicable regulations) recommended sanitization intervals.

No exceptions.

- 2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function
 - **a)** Describe how the effectiveness of sanitization procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections, etc.).

The veterinary staff monitors animal enclosure sanitation visually during rounds of facilities and it is done by Army Animal Care Specialists bimonthly and by the IACUC during semiannual facility inspections. Maintenance dive staff visually assess and clean pens/nets monthly. Microbiological monitoring of open ocean enclosure surfaces is not deemed necessary. Fishhouse sanitation is monitored and tested monthly and by Army Animal Care Specialist technicians.

b) Describe preventive maintenance programs for mechanical washers.

N/A

f. Waste Disposal [Guide, p. 73-74]

Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse

No soiled bedding is produced. Covered waste receptacles are staged at each pier for receipt of incidental trash. Boxes from fish cases are placed in re-cycling bins staged by each fish house. Contract housekeeping empties administrative spaces' trash receptacles daily. Waste fish are kept frozen in a separate container dedicated for that purpose or clearly labeled "DO NOT USE". When full, the fish are removed by a contractor to be rendered. Fish debris from bucket cleansing is disposed of through an inline utility grade disposal in the fish houses.

ii. Animal carcasses

Animal carcasses from necropsy are handled in accordance with the bio-hazardous waste plan. They are double-bagged in red plastic bio-hazardous waste bags bearing the program address, and placed in a marked freezer located in a controlled access fenced area, adjacent to the pathology lab dedicated to that use, until pick up by a contract hazardous waste hauler (Stericycle Medical Waste Services). Any dead water-birds or other wildlife found on site are handled the same way. Pickups are on on-call schedule

iii. Hazardous wastes - infectious, toxic, radioactive, sharps and glass

All hazardous wastes are removed from SSC Pacific under contract with a medical waste disposal contractor. Animal tissues are placed in red plastic, center labeled, bio-hazardous waste bags inside marked cardboard boxes and frozen until removal. Contaminated clinical materials, (blood soaked sponges, gloves, specimen swabs, fecal containers, etc) are placed in a red plastic, center labeled, bio-hazardous waste bag staged in a receptacle in the clinical lab. Weekly, this bag is sealed and placed in the bio-hazardous waste freezer until removal from SSC Pacific every 30 days. Sharps are placed into red plastic biohazard sharps containers. When three fourths full, these are also placed in the biohazard freezer until removal every 30 days.

g. Pest Control [Guide, p. 74]

i. Describe the program for controlling pests (insects, rodents, predators, etc.) noting the control agent(s) used, where applied, and who oversees the program and applies the agent(s). Include a description of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

Air curtains are in place on all external opening doors of the fish houses. Plastic veil curtains are in place on all external opening doors to freezer spaces. Doors to fish houses are secured in closed position when areas are not in use. Trapping and removal of feral cats and placement of rodent bait boxes is performed, as needed, by contracted services under the

direction of Navy Facilities (NAVFAC). A deterrent electrical wire system is in place on perimeter decks of pens to discourage haul-out by wild sea lions. As a Federal activity, through consultation with NOAA Fisheries and U.S. Fish and Wildlife Services (as appropriate by species), SSC Pacific is authorized to relocate nuisance animals.

ii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

Pesticides are not used near the animal enclosures.

h. Emergency, Weekend and Holiday Care [Guide, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (e.g., regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed. Indicate qualifications of weekend/holiday staff if not regular staff.

Many marine mammal projects conduct regular training sessions on holidays and weekends. If projects are not conducting regular training sessions on these days, training and animal care personnel are scheduled to provide care and feeding of the animals. At each session or feeding animals are observed for any indication of injury or illness. A rotating oncall roster is in place for the duty veterinarian and animal care technician who are available 24/7, 365. The duty veterinarian is immediately contacted if any problem is observed or suspected.

ii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

A Standard Operating Procedure for obtaining emergency veterinary care is in place (Division SOP #2, CONTACTING VETERINARY STAFF IN CASE OF ANIMAL EMERGENCY). An on-call veterinarian is available 24 hours a day, and is contacted through the central duty vet phone (619-553-5077). The on-call Animal Care Specialist is also available 24 hours a day and uses the tech phone (619-607-8078). In the event of an emergency the reporting individual communicates directly to the on call veterinarian. The technician follows with emergency equipment. Stateof-the-art portable equipment for advanced life support including endotracheal intubation, intermittent positive pressure ventilation, oxygen supplementation, cardiopulmonary resuscitation drugs, and patient monitoring are continuously staged in the clinical facility and at each animal pier. A recall list is maintained and posted to allow contact of all responsible supervisory and support personnel. The Command Duty Officer is briefed on the procedures for recall in the event of an animal, facilities, or natural disaster emergency.

2. Population Management [Guide, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands, etc.).

Each animal is administratively assigned a unique alphanumeric designator. The first two characters are the first letters of the genus and species name, followed by a three digit sequential number and an M or F for male or female respectively. Designators are assigned at acquisition or birth of the animal. However, no dolphins have been wild caught since 1989. Animals at the MMP are recognized by animal handlers and veterinarians based upon unique physical and behavioral characteristics. Additional video or still images are captured as deemed necessary for visual identification, e.g., dental arcades, distinguishing scars. Few animals have been implanted with temperature probes that also have unique numeric identifiers assigned to them. Routinely now, DNA is collected on every MMP animal and archived at Portland State University.

b. Record Keeping

Describe procedure(s) for maintaining individual records on animals. Identify the species for which individual records are maintained, individuals (titles, not necessarily names) responsible for maintaining the records, and where they are maintained and how veterinary and IACUC/OB access is assured.

A comprehensive animal care records database (Microsoft Access) is used for all animal records. Data entry includes medical observations, laboratory values, treatments, procedures, transport history, morphometrics, diet, and training information. This database allows clinicians, trainers, and researchers to perform advanced, epidemiology based, queries with the aim of improving animal care. A paper record file on each animal is kept in designator sequence in the secure records room. The file contains hard copy sections for: medical observations, statistical analyses of reported laboratory results, morphometrics, transport history, and medication history. Also included are original copies of all examination and laboratory reports. All animals have a dedicated videotape and digital recording library (Osirix and the Elkin Rapid Store Rapid View) for recording all diagnostic imaging procedures. These are maintained in the clinical area. All animals are included in our comprehensive digital image management system. Records of deceased animals are archived indefinitely in a separate file. Data are routinely archived on CD.

c. Breeding, Genetics and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

N/A

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of all animals used in a study.

N/A

iii. For newly generated genotypes, describe how new phenotypes that negatively impact well-being will be monitored, managed and reported to the IACUC/OB in a manner to ensure the animals' health and well-being.

N/A

III. Veterinary Care [Guide, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [Guide, pp. 106-109; Ag Guide, pp. 8; 45; 51-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (e.g., from commercial vendors, other institutions, etc.).

Dolphins and sea lions (non releaseable to the wild) are occasionally procured from stranding facilities. A review of potential animal records and laboratory data is conducted and consultation with source veterinarians takes place. In addition, sea lions were collected from the wild in 2013 in accordance with 10 USC 7524. Only animals considered healthy and fit for duty/transport are procured.

2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

Sea lions procured from outside sources are transported to San Diego in accordance with SOP #22, "Transporting Navy Seal Lions". Sea lions are transported in cages in open backed government vehicles or in the back of an air-conditioned leased panel truck. A handler accompanies sea lions at all times. Sea lions may be moved within "transport" cages or unconfined aboard small boats.

Dolphins and whales are transported long distances in Animal Transport Containers (ATC's) in accordance with Division SOP #21, TRANSPORTING NAVY CETACEANS. Short term over-water transports of dolphins are routinely conducted in "beaching trays" as part of open water training or work activities. While aboard small boats, dolphins are moved inside the padded trays, which provide shielding from the sunlight, and access for keeping the animal cool and

wet. For longer transport, cetaceans are transported in ATC's in the back of trucks and in various military aircraft. They are accompanied by a veterinarian and attended to by animal handlers at all times. An ATC consists of a custom fitted, synthetic, fleece lined stretcher with openings for the animal's pectoral flippers and contoured to the flukes, suspended by aluminum poles in brackets which are mounted on a 128" x 32" x 30" (inside dimensions) fiberglass container on pneumatic wheels. The container is filled with water at a level to keep the animal comfortable. Additional fresh water is provided by hand held sprayers to keep the animals wet and cool.

Animals are quarantined as necessary as a biosecurity measure.

B. Preventive Medicine

- **1. Animal Biosecurity** [Guide, pp. 109-110]
 - **a.** Describe methods used to monitor for known or unknown infectious agents.

Prior to procurement of new animals, extensive examination and diagnostic testing is performed. All newly acquired or recently returning animals are quarantined as described below, and diagnostic screening tests are conducted to monitor for infectious agents. A staff Epidemiologist continuously monitors disease outbreaks in other wild and captive populations, as well as disease outbreaks in the MMP population. Screening methods include but are not limited to bacteriology, viral, cytology, fungal assays, titers, polymerase chain reaction (PCR), and gene sequencing.

b. Describe methods used to control, contain, or eliminate infectious agents.

Admixing of species is not practiced. All sea lions are maintained in enclosures at least 30' away from cetacean sites with the exception being animals housed in temporary land based enclosures when enclosures may be closer but never allow physical or visible aerosol contact. Generally health concerns are treated while the animal remains in its usual social group. For treatment or examination purposes the animal may be separated into an enclosure alone. If a contagion was suspected or other requirements for isolation existed, isolation facilities as above would be utilized. Pregnant or lactating and juvenile cetaceans are separated as described above. The Navy employs no female sea lions.

Animals returning from a deployment are kept separate until it is determined through titers, PCR, post deployment physical exams and disease agent isolation attempts that they are healthy and free from contagious disease IAW Division SOP #25, QUARANTINE OF MARINE MAMMALS.

In the event of an infectious disease outbreak, MMP Clinical Veterinary Services SOP # 21, MINIMIZING THE SPREAD OF INFECTIOUS DISEASES and Division SOP # 8, MINIMIZING DISEASE TRANSFER

BEWTEEN MARINE MAMMALS, HUMANS, AND OTHER ANIMALS, would be followed.

2. Quarantine and Stabilization [Guide, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

Animals being considered for procurement are subject to various procedures including full physical exam, full body ultrasound, fecal, urinalysis, radiographs, blood work, and various biologic sample collection to screen for pathogens.

b. Describe quarantine procedures for each species that are purpose bred.

The Navy MMP does not acquire purpose bred animals. Sea lions are either acquired from rescue/stranding organizations, or wild-caught.

c. Describe the quarantine facilities. In your description explain any special measures used for quarantine/conditioning of each random source (not bred and raised specifically for research) species used.

Quarantine procedures are followed according to Division SOP 25-10 "Quarantine for Navy Marine Mammals".

New sea lions are isolated from the population for a period of at least 14 days for acclimation and medical quarantine. Isolation enclosures for sea lions are maintained at land based quarantine near (b)(3) If required, the complex can be removed to a remote area

No new dolphins are currently acquired or bred at this time. In the unforeseen event that isolation of a dolphin was deemed necessary animals may be placed at remote sites, such as NAB or placed in a land based pool.

All animals returning from a deployment or satellite facility are subject to quarantine procedures IAW Divisional SOP 10-25. Quarantine is achieved by separating animals by at least one pen distance (30 feet) from the main population. If higher level of quarantine is needed as determined on a case by case basis by the Attending Veterinarian, closed system or open system pools may be utilitzed near (b)(3)

d. Describe the required/recommended stabilization period for each species.

The stabilization period is equal to or greater than the quarantine period, and is established on a case-by-case basis with guidance from the Attending Veterinarian. During this time, animals are typically not subject to the same work or training activities as the main population.

e. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

Dolphins and sea lions are not normally mixed. Sick animals requiring extensive care or monitoring are maintained in the hospital pens, land based pools at(b)(3) Breeding animals are maintained in the pens on (b) Dolphins involved in fleet activities, or in training, are normally had listed at (b)(3) and separated by gender. Sea lions involved in fleet activities are housed at (b)(3) Social groupings are based on age, sex, health status, and fleet system. All attempts are made to provide necessary medical treatment to animals while maintaining their social groupings.

3. Separation by Health Status and Species [Guide, pp. 111-112]

a. Describe isolation procedures and related facilities for animals.

Admixing of species is not practiced. Dolphins are maintained in separate but adjacent enclosures. Visual, acoustic, and limited physical contact is possible through adjoining nets. All sea lions are maintained in enclosures at least 30' away from cetacean sites with the exception being animals housed in temporary land based enclosures when enclosures may be closer but never allow physical or visible aerosol contact. Equipment used for the different species is maintained separately. Isolation enclosures for sea lions are maintained at (b)(3) If required, the complex can be removed to a remote area. In the unforeseen event that isolation of a dolphin was deemed necessary animals may be placed in portable enclosures at remote sites and away from other animals or placed in a land based pool.

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

None foreseen.

4. Surveillance, Diagnosis, Treatment and Control of Disease [Guide, pp. 112-113]

a. Describe 1) the procedure(s) for daily observation of animals for illness or abnormal behavior, 2) the observer's training for this responsibility, and 3) method for reporting observations (written or verbal). Include a description of the method for ensuring that reported cases are appropriately managed in a timely manner.

Each animal is subject to a medical check by the assigned trainer/animal care staff as a part of the daily training routine. The staff member fills out a daily record which is placed weekly into the animal's electronic record. All trainers/animal care staff have received instruction, which is documented, on how to recognize potential health problems or risks. Each animal is handled,

hand fed, and interacted with on an individual basis each day. Trainers/animal care staff immediately report any suspected health concerns to the clinically assigned veterinarian. This veterinarian directly observes every animal at a minimum frequency of once a week but generally more often.

b. Describe the methods of communication between the animal care staff/veterinarians and the researcher(s).

Researchers/trainers have cell numbers for all the veterinarians and for the oncall veterinarian and technician. Researchers and trainers also work in close proximity with the veterinary staff, and they interact on a daily basis to communicate animal care issues.

c. Describe the procedure for providing veterinary medical care to ill animals and note who is contacted and the method of communicating (written or verbal) information to the veterinarian regarding sick animals.

All health concerns are brought to the direct attention of the Attending Veterinarian or a staff veterinarian. Following appropriate examinations and diagnostics, a treatment plan is formulated. Any prescription medications are ordered and an individual treatment record is completed by the veterinarian and given to the Animal Care Specialists. The Animal Care Specialist dispenses the medication in containers labeled with the animal's name, designator, date, medication type and amount, instructions for administration, and prescribing veterinarian. Other interventions requiring animal restraint, (e.g., oral fluid administration, manual feeding, etc.), are coordinated by the responsible trainer and the veterinarian. These activities are documented on a clinical procedure form.

d. Describe the preventive medicine and health management/ monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals, etc.) for each species.

The emphasis of the veterinary care program is a six part comprehensive preventive medicine approach;

- 1) All Navy marine mammals undergo complete annual physical examinations-Fleet and fleet support animals are also examined semiannually. These in depth examinations include observation, palpation, percussion, ballotment, auscultation, nasal cytology/microbiology, fecal parasitology, hematology, serum biochemical analyses, full body sonography, and morphometrics. Prior to transport of a candidate animal, a pre-transport health assessment is performed to include observation, palpation, percussion, ballotment, auscultation, hematology, and serum biochemical analyses.
- 2) Animals are weighed monthly and their weight is maintained within target guidelines for each animal. Guidelines are established with input from historical morphometrics of the individual animal, statistical analyses of free

ranging, Navy, and other captive population data, the trainers and attending veterinary staffs. A monthly summary report is generated by the record staff, reviewed by the attending veterinarians, and distributed to all veterinary and supervisory personnel. Animal weights are maintained or adjusted using a customized ration formulation for each animal. The ration formulation is based on the caloric and nutritional analysis.

- 3) The veterinary staff maintains an extensive medical database. Each animal has an individual medical record maintained on traditional paper records as well as on computer disc. All data is also entered into a large computer database for future use in medical decision making.
- 4) To provide the above support in an operational setting a veterinarian accompanies all animals transported on deployment.
- 5) A complete necropsy examination is performed upon the death of any animal and all resulting information is used in preventive medicine program reviews.
- 6) Lastly, a commitment to improvement in preventive medicine and clinical care is demonstrated in direct and supported investigations into advanced clinical technologies. Animal health monitoring is accomplished by the daily observations and reports and the tracking of animal morphometrics, results of laboratory analyses and known medical problems through the records systems and databases.

C. Clinical Care and Management [Guide, pp. 113-115]

1. Emergency Care [Guide, p. 114]

a. Describe the procedures to ensure that emergency care is continuously available for animals during and outside of regular work hours.

All veterinarians carry a cellular telephone. The on-call veterinarian forwards the duty phone number to his/her cell phone and is available 24 hours a day. The on-call Animal Care Specialist is also available 24 hours a day. An emergency response Standing Operating Procedure (Division SOP#2, CONTACTING VETERINARY STAFF IN CASE OF ANIMAL EMERGENCY) is in place. "State-of-the-art" portable equipment for advanced life support including: endotracheal intubation, intermittent positive pressure ventilation, oxygen supplementation, cardiopulmonary resuscitation drugs, and patient monitoring are continuously staged in the clinical facility and at each animal pier.

b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The Attending Veterinarian has the authority, delegated by the IO and IACUC, over all animals in the program regarding emergency treatment, removal from experiments, relief from pain or distress, and euthanasia. In cases where emergency euthanasia is warranted, time permitting, a veterinarian contacts the Attending Veterinarian, Biosciences Division Head., and Senior Scientist. All cases of emergency treatment are reportable to those mentioned above, as well as the IO.

2. Clinical Record Keeping [Guide, p. 115]

Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who has access to the records. Describe the role of the Attending Veterinarian in record keeping.

The staff veterinarian enters medical observations, diagnostics, treatments, and procedures in a central electronic database immediately after the action. The Record Office is responsible for maintaining the records database and transferring the electronic medical records to the paper record daily. Completed treatment records are archived in the animal's paper record after review by the veterinarian. A copy of all pending clinical laboratory accessions is retained in the clinical lab and reviewed daily. Results reviewed by the assigned, clinical veterinarian are placed in an update box and transferred to the animal's record by records personnel daily. Every animal has a dedicated video file stored in one of two storage systems (Osirix and Elkin Rapid Store Rapid View). A comprehensive electronic image management system is used to archive all diagnostic imaging procedures (i.e., sonograms and video endoscopic examinations). Five contract employees have full time oversight responsibility of the animal medical records and databases. Veterinarians are responsible for data input of medical observations and treatment orders as outlined above. Completed treatment records are reviewed and initialed by the veterinarian and archived in the animal's medical record. The Records Office staff ensures all medical records are completed as required, and the Attending Veterinarian is responsible for ensuring all veterinarians complete the records in a timely manner. The Records Office is located in a secure room, and access is only allowed to the Records Office staff and veterinarians.

- **3. Diagnostic Resources.** Describe available diagnostic methods used in the program including:
 - **a.** In-house diagnostic laboratory capabilities.

In house laboratory assets include: Sediplast® erythrocyte sedimentation rate (ESR) determination system, microhematocrit centrifuge and reader, refrigerated digital centrifuge, serum refractometer, seawater refractometer, microscope(s), Diff-Quick® or equivalent staining system, hemoglobinometer, Fecalyser® fecal floatation system, an I-Stat™ point-of-care serum chemistry and blood gas analyzer, and dip-stick urine and whole blood chemistries. A NOVA stat blood analyzer provides immediate blood gas and basic chemistry values for interoperative and emergent clinical cases. Portable I-Stat chemistry analyzers are also available for deployment use. A Unipette® system hemocytometer chamber is available but not often used. ESR, Hct, fecal flotation and blowhole cytology is routinely done in-house.

b. Commercially provided diagnostic laboratory services.

Clinical pathology, microbiology and histopathology services are available at Naval Medical Center San Diego (NMCSD) and through a contract for Antech diagnostics. Clinical samples are prepared (serum separated, specimens labeled, requisition forms filled out) by the Animal Care Specialist or laboratory assistants. A specimen cooler is staged at the guard station to hold samples until Antech courier pick up or specimens are delivered directly to NMCSD by the Animal Care Specialists. Each morning the previous day's routine reports are downloaded, imported into the database, printed, and placed in the attending veterinarians' box for review. STAT orders allow results to be transmitted within several hours of sample collection. In addition to the above mentioned NMCSD Core Lab, Antech Diagnostics, Joint Pathology Center, and Oklahoma State Diagnostic Lab, the USDA National Veterinary Services Laboratory (NVSL), and the DOD Veterinary Diagnostic Laboratory at Ft Sam Houston, TX, laboratories are used for toxicological analyses, diagnostic virology, proximate analyses and other services on an as needed basis. Many other commercial laboratory services are solicited and utilized as needed to meet the needs of the investigation, (e.g. milk and blubber analyses for mineral, heavy metal and organochlorine content, various mycology and serology, etc

c. Necropsy facilities and histopathology capabilities.

A 411 ft2 necropsy facility, and 255 ft2 archive (b)(3) is located in (b)(3) The facility is equipped with a plumbed, stainless steel pathology table, a wide array of knives, bone cutters, striker saws, scales, collection jars, etc. A tissue preparation station with, water source, is used for fine dissection and cassette loading. A fume hood workstation is present. The staff veterinarians assisted by the Animal Care Specialists and laboratory assistants perform gross necropsies. Tissues are routinely fixed in 10% neutral buffered formalin, trimmed and loaded into cassettes and forwarded to Joint Pathology Center (JPC) for histopathologic analyses. Occasional tissues are harvested into Karnovsky's or other required fixative on special request. Formalin fixed tissues are archived in closed, vented cabinets. Formalin fixed paraffin embedded tissues and stained glass slides are archived in a temperature controlled room in (b)(3)

d. Radiology and other imaging capabilities.

The diagnostic facility is equipped with a 300mA, 150kVp portable diagnostic x-ray generator axquaired in 2006 and the Elkin MK5 Digital Radiology machine. Digital radiography equipment includes Eklin Image management system (Rapid PaCS-SF), Mark5 digital radiology system, Poskom and GE AMX-4 radiology tubes. Uso of the equipment is under the program use permit promulgated by the Radiation Safety Officer. Protective aprons, protective gloves and thyroid shields are used. Only approved, trained users

who wear personal dosimetry badges are permitted to operate the equipment. Controlled access barriers are in place during exposures. All exposures are logged to include date, patient/view, technique, operating personnel, location and exposure comments

Other diagnostic imaging equipment includes a Pentax Image Management System for digitized management of diagnostic images. This system supports six fiber optic endoscopes of various configuration a dn two video endoscopes. Laparoscopic equipment includes a Karl Storz laparoscopic system. A GE Vluson-I ultrasound with a variable transducer from 2.5-7.5 MHz, Doppler capability, and an endoscope guided ultrasound transducer provides diagnostic sonography images Two M-Turbo ultrasound units including two 3.5 MHz and two 5.0 MHz transducers provide sonsography capability.

4. Drug Storage and Control

a. Describe the purchase and storage of controlled and non-controlled drugs.

All controlled substances are held in a security container under a double lock system. Only trained and authorized staff veterinarians have access to this container. Controlled drugs are acquired from the Navy Medical Center San Diego controlled drug pharmacy. A monthly accountability inventory is conducted on all controlled substances. Non-controlled drugs are kept under lock and key in the combined pharmacy and clinical pathology area in (b)(3)

Veterinary specific controlled drugs are sources commercially, are also inventoried monthly and held under the same double lock system. Some sources of non-controlled drugs include (b)(3)

All drugs and supplies are tracked on the (b)(3)

database maintained by the Animal Care Specialists. The database incorporates expiration date and prompts disposal and reorder of all

b. Describe record keeping procedures for controlled substances.

A designated Army Veterinary Corps Officer serves as the Controlled Drug Custodian and coordinates monthly Disinterested Officer Inventories. Quarterly controlled drug inventories are performed by NMCSD (Navy Medical Center San Diego) personnel. Expired controlled drugs are disposed of IAW MMP Clinical Veterinary Services SOP 8, CONTROLLED DRUG INVENTORY, DISPENSING, AND DISPOSAL.

All inventory changes are logged in accordance with Navy and local command regulations.

D. Surgery [Guide, pp. 115-123]

1. Pre-Surgical Planning [Guide, p. 124]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and postoperative care.

All surgical procedures are clinical and directed by the Attending Veterinarian on a case by case basis. All procedures are performed in the surgery/treatment suite of (b)(3) or on location at the discretion of the attending veterinarian with the animal's safety and welfare as the basis for the decision. The AV designates a clinical veterinarian to supervise each surgical procedure, assign personnel, locate equipment, select drugs and anesthesia agents, and provide pre and postoperative care.

2. Surgical Facilities [Guide, p. 116]

a. List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. Include areas where surgical procedures are conducted in agricultural species. Indicate the type of species, nature of procedure (major/minor/emergency; survival and non-survival, etc.). Indicate for each surgical area if the use is heavy (daily), moderate (weekly), or light.

Surgical procedures are not normally approved for IACUC protocols at the MMP. All surgical procedures are survival, driven by clinical need, and directed by the Attending Veterinarian on a case by case basis. All procedures are performed in the surgery suite ((b)(3) 330 ft²) or treatment suite (b)(3) 545ft²) of (b)(3) or on location at the discretion of the attending veterinarian with the animal's safety and welfare as the basis for the decision.

b. List the major surgical support equipment available at each location where survival or nonsurvival surgery is performed (e.g., gas anesthesia machines, respirators, etc.).

Two large animal anesthetic machines equipped with sevofluorane vaporizers (Mallard 2800C), Bird® mechanical respirators, and custom cetacean apneustic plateau control devices are on site. The surgery/treatment suite is equipped with a B650® patient monitor purchased in 2014. This equipment is capable of displaying patient rectal and surface temperature and arithmetic difference, hemoglobin-oxygen saturation and pulse plethismograph (noninvasive), ECG waveform (up to five leads) and heart rate, respiratory rate, breath-by-breath airway gasses (oxygen, carbon dioxide, anesthetic agent) and two channels of vascular pressure (invasive). The data is displayed real time and patient trends can be displayed on command numerically or in waveform. Alarm limit settings for all parameters are customized. Permanent paper recordings can be produced as well as PC data interface to directly download data to patient's medical record. Additional surgery/treatment suite support equipment includes: Dash 4000® portable patient monitor and, two Lifepak® defibrillation/monitor units, custom cetacean table, suction apparatus, peripheral lighting, a bipolar electro-coagulation/cautery system, liquid nitrogen cryosurgery unit, and fluid administration equipment.

c. Describe any specialized considerations for designation of surgical areas (e.g., rodents, aquatics, farm animals, etc.).

Minor and emergency procedures may occasionally be performed in field conditions if necessary and at the discretion of the Attending Veterinarian. In these cases, the animal is still subject to the same standards in aseptic technique, sedatives, analgesics, anesthetics, and conditions as described above.

3. Surgical Procedures [Guide, pp. 117-118]

a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique, etc.).

Surgical procedures are not normally associated with a research protocol and are normally only performed for clinical reasons. Most surgery performed is classified as minor, survival surgery.

b. How is non-survival surgery defined?

Non-survival surgeries (where patient dies or is euthanized at the end of the procedure) are not performed at the MMP.

4. Aseptic Technique [Guide, pp. 118-119]

a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

All surgical procedures are clinical cases. Standard aseptic technique includes patient preparation (disinfection of surgical site), preparation of the surgeon (sterile gown, face mask, sterile gloves), sterilization of surgical instruments and supplies, and aseptic surgical technique. Procedures requiring general anesthesia are normally performed in (b)(3)

b. Describe methods used to sterilize instruments and protective clothing. Indicate how effectiveness of sterilization is monitored and, if applicable, any approved alternate methods for instrument re-sterilization between serial surgeries. If used, include a description of approved <u>liquid sterilants</u> and instrument exposure time(s) required for each.

Sterilization of equipment and protective clothing is performed in standard fabric, paper, or (b)(3) wrappers, or equivalent. (b)(3) and (b)(3) tape is used to confirm sterilization. Ethylene oxide sterilization is available at the Naval Hospital for use as needed. The laboratory also is enrolled in the Proper Biological Test Pack and Culture Service Program for the Protection of Patients and Staff which provides for the routine monitoring of the sterilizers in use as one aspect to

adhering to the guidelines recommended for infection control by the U.S. Department of Health and Human Services Public Health Service and Centers for Disease Control.

c. Describe surgical support functions provided by the program to investigators.

Surgical procedures are not normally associated with a research protocol and are normally only performed for clinical reasons.

5. Intraoperative Monitoring [Guide, p. 119]

Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

A veterinary staff member is assigned to monitor and record every medical procedure, including surgical procedures, for the duration of the procedure. Vitals are recorded every five minutes onto an Anesthesia Monitoring Form, and include heart rate, respiratory rate, pulse oximetry, tidal volume, gas and oxygen flow, temperature, end tidal CO2.

6. Postoperative Care [Guide, pp. 119-120]

Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

Follow up monitoring of all surgical sedated, or anesthetic cases is performed by the veterinarian. Animals recover from general anesthesia under constant observation of the veterinarian and animal care staff in the surgery/treatment suite (b)(3) Animals are not returned to the water until cleared by the veterinarian. The Animal Care Specialist or training personnel under the direction of the veterinarian may administer post-procedure care. The use of analgesic agents in recovery is under the direction of the veterinarian. The post-procedure observations are entered into the medical records in the same format as all observations.

E. Pain and Distress [Guide, pp. 120-121]

1. Describe how and by whom pain and distress are assessed and categorized.

The Attending Veterinarian reviews every protocol prior to distribution to the IACUC to ensure that pain and distress events are properly identified, assessed, and categorized. There are currently several protocols approved by the IACUC that require the use of analgesics/anesthetics (other than topical local anesthesia) which will be administered/dispensed by a veterinarian.

2. Describe how the IACUC/OB ensures that unnecessary pain and distress are avoided (e.g., pilot studies, monitoring by veterinary staff, animal use protocols, humane endpoints, other refinements, etc.).

All procedures are monitored by veterinary staff, all of whom are specifically trained to recognize signs of animal pain and distress. Animal trainers are also sensitive to perception of animal pain and distress, and assist the veterinary staff in recognizing signs. Animals are provided analgesics and anesthetics as necessary to relieve pain or distress, and the Attending Veterinarian supervises administration of all drugs. If an animal is experiencing unacceptable distress that cannot be controlled, the procedure is terminated and the animal is returned to its enclosure.

F. Anesthesia and Analgesia [Guide, pp. 121-123]

1. List the agents used for each species. Dosages, routes of administration and drug combination should be included in guidelines and available at the time of the site visit. Describe also any non-pharmacologic means used to diminish pain and distress.

Agents used for anesthesia and analgesia of both pinnipeds and cetaceans include: diazepam, midazolam, ibuprofen, carprofen, sevoflourane, lidocaine, medetomidine, meperidine, butorphanol, tramadol, alfaxolone. Current dosages/routes on approved protocols are:(b)(3)

Animals are routinely desensitized to common medical and husbandry procedures in order to reduce distress associated with these procedures. Ice packs are used topically prior to blubber biopsies.

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

The veterinary staff is responsible for administering analgesia and anesthesia in most protocols and all clinical cases. In the rare event that a researcher needs to choose their own anesthetics or analgesics for their specific protocol, the researcher is required to seek guidance from the Attending Veterinarian prior to submitting the protocol for IACUC review. In these cases the veterinary staff is still responsible for administration of all drugs and anesthesia. Pinnipeds are generally premedicated with atropine, diazepam, midazolam, medetomidine, and occasionally meperidine. Induction is accomplished with sevoflurane delivered by custom mask. Endotracheal intubation and maintenance on sevoflurane is standard protocol. Cetacean general anesthesia is rare. In those cases to date, induction has been with propofol i.v. followed by endotracheal intubation and maintenance with isoflurane or sevoflurane delivered in a semi-closed circle circuit by a respirator modified with an apneustic plateau device capable of providing intermittent positive pressure ventilation of cetacean species.

3. Describe the monitoring of the effectiveness of anesthetics and analgesics, including who does the monitoring.

The use of all medications is only under the direction of a staff veterinarian. Veterinary technicians and veterinarians provide for the monitoring of all animals. The veterinary staff is trained to recognize specific indications of pain or distress during anesthesia, and monitoring parameters are recorded on an anesthesia and/or procedure form.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

To date, no research protocols have included the use of neuromuscular blocking agents, and these types of procedures are generally not considered for research projects involving the Navy marine mammals. Neuromuscular agents are occasionally used in clinical cases, in which the Attending Veterinarian specifically approves and supervises.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

As anesthetic procedures are used infrequently for marine mammals, all equipment is extensively tested and assessed for proper function prior to every procedure. Normally the veterinary staff will prepare and check the equipment, and the veterinarian in charge of the procedure will double check prior to the procedure. Preventative maintenance is performed approximately every 18 months or sooner if needed.

G. Euthanasia [Guide, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter. Include consideration of species, age, condition (e.g., gestational period, or neonatal) and location(s) for the conduct of the procedure.

Due to the nature of the program, protocols involving the euthanasia of animals either for research purposes or planned euthanasia as part of the protocol are not normally performed; however, any such procedure would require Institutional Animal Care and Use (IACUC), Senior Scientist for Animal Care, Scientific and Veterinary Support Branch Head and Biosciences Division Head approval after thorough examination of the procedures. Outside of a research protocol, euthanasia is typically performed on a case-by-case basis at discretion of the veterinarian to relieve excessive pain or distress that cannot otherwise be alleviated. Approved euthanasia methods are consistent with the most recent AVMA Guidelines on Euthanasia. Intravenous injection of a barbiturate euthanasia solution is the method of choice. Policies are IAW MMP Clinical Veterinary Services SOP #17, ANIMAL EUTHANASIA.

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

N/A

3. Describe the methods used to confirm death of an animal.

Animals are confirmed dead through the use of EKG monitoring, cardiac auscultation and cardiac palpation.

IV. Physical Plant [Guide, pp. 133-151]

Repeat this section for each animal housing area, including agricultural settings, temporary holding areas for field studies, aquatic environments, and each IACUC/OB approved satellite housing facility. Include as an appendix the floor plans of each (if applicable) on 8.5" x 11" or A4 paper.

A. Location and Construction Guidelines

1. Note the location (building, floor, wing, etc.) of the animal facility(ies). Describe the management structure and program oversight for each of the areas listed in this section.

All Biosciences Division facilities involving research animals are located at the Naval Base Point Loma Bayside complex of the parent command, SSC Pacific, on the west shore of San Diego Bay. The surgical/treatment suite is located in the lower level of (b)(3) which is at the head of (b)(3) See Appendix 3 for Summary of Animal Housing and Support Sites. See Appendix 4 for floor plans and Site Map.

2. Describe the physical relationship of the animal facilities to the research laboratories where animals may be used.

There are no physical facilities dedicated as research laboratories where animals are used. Animals on research protocols are generally housed within normal social groupings in open-ocean floating net enclosures. Occasional, short term holding of an animal in an ATC or SFD pool is performed, usually at (b)(3)

3. Describe the general arrangement of the animal facilities (e.g., conventional, clean/dirty corridor, etc.). For animals that are maintained in a laboratory in order to satisfy the scientific aims of a protocol, describe the housing and care provided and the maximum period of stay required.

This facility is unique in its animal population, use, and application. The facility is a unique marine mammal facility and as such supports the clinical care of marine mammals housed in open-ocean enclosures. Animals are transported to the physical veterinary facilities for short-term diagnostic or treatment procedures only. This facility would be considered a conventional facility by design and function.

4. Describe finishes throughout the animal facility(ies) for floors, walls, ceilings, doors, alleyways, and gates. Note any areas that are not easily sanitized and describe how these areas are maintained.

Animal housing facilities are cleaned in accordance with SOP 18-10 "Animal Enclosure and Pier Area Cleaning, Sanitation, and Maintenance". All decks and walkways surrounding animal enclosures are cleaned daily with a high pressure hose, steam cleaner, and/or cleaning broom to remove debris. Foreign material or excess plant material is removed from enclosure areas. Netting is cleaned as necessary to limit plant growth.

The treatment facility and surgical room contain nonporous surfaces for the walls, floor, ceilings, and doors that are easily sanitized. These areas are cleaned before and cleaned and sanitized after every procedure.

5. If <u>exterior windows</u> are present within the animal housing or procedure areas, describe IACUC/OB consideration regarding temperature and photoperiod control, as well as potential security risks.

N/A

B. Functional Areas and Operations

- 1. Heating, Ventilation, and Air-Conditioning (HVAC) [Guide, pp. 139-140, 143]
 - **a.** Describe the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as the use of variable air volume (VAV) systems, and additional key features of HVAC systems affecting performance.

The Veterinary Hospital has an HVAC system to maintain proper temperature and pressure gradient for the surgery room. Each room has separate thermostat control to maintain proper temperature. The surgery (b)(3) has the ability to create positive pressure gradient when in use and has a (b)(3) indicator for pressure gradient. All animals are housed in outdoor pens and do not require additional temperature, humidity, or air pressure control.

b. Describe construction features that minimize the potential for adverse consequences to animal well-being, such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems.

N/A – animals are housed in open ocean enclosures.

c. Describe how critical air pressures, ventilation, and temperature are monitored and maintained in the event of a system or component failure.

N/A – animals are housed in open ocean enclosures.

d. Describe procedures for monitoring animal facility mechanical systems and notifying appropriate personnel in the event of a significant failure that occurs outside regular work hours.

N/A – animals are housed in open ocean enclosures.

2. Power and Lighting [Guide, p. 141]

a. Note if emergency power is provided for the animal facility and if so, what electrical services and equipment are maintained in the event the primary power source fails.

Electrical power to the command is supplied through San Diego Gas and Electric. 110 V, 60 Hz, AC power is available in emergency situations through the use of several gasoline powered portable generators and a 40kW diesel generator.

b. Give history of power failures for the animal facility. Note frequency and duration. If emergency power was not available during a power failure, describe steps taken to ensure the comfort and well-being of the animals and the temperature extremes reached in the animal rooms during the failure.

One unplanned power outage occurred in calendar year 1994. Service was interrupted to the entire Point Loma Federal Complex area for approximately 3.5 hours. Successful implementation of backup generator use, in accordance with SSC Pacific emergency plan, was finished within one hour from onset. No loss of refrigeration system integrity or animal care capabilities was experienced. Planned outages for maintenance are pre-scheduled. Another unplanned power outage occurred in calendar year 2011. Service was interrupted for a large portion of Southern California. Successful implementation of backup generator use, in accordance with SSC Pacific emergency plan, was finished within one hour from onset. No loss of refrigeration system integrity or animal care capabilities was experienced.

c. Describe lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity, photoperiod (Light:Dark), construction features (e.g., water resistance), and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms.

Animals are housed in open ocean pens with ambient natural light. Within the veterinary hospital, (b)(3) conventional overhead, shielded fluorescent lighting is present. Auxiliary surgery lights in (b)(3) Receptacles are all outdoor grade and covered.

3. System Malfunctions. If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. <u>AAALAC International Rules of Accreditation (Section 2.f)</u>

No animal losses or health problems due to power outages or other life support system failures have occurred.

4. Storage Areas [Guide, pp. 141-142]

 Describe storage areas for feed and bedding, including temperature and vermin control.

The bulk of the marine mammal subsistence (frozen fish) is stored at (b)(3) On site fish storage is in dedicated freezers in (b)(3) (475ft2) and (b)(3) (426ft2). Fish freezers are maintained at 0C or lower, with a built-in alarm system. The Command Duty Officer responds to all reports of mechanical problems during non-duty hours. Navy Public Works personnel are available on emergency recall 24 hours a day. Trapping and removal of feral cats and placement of rodent bait boxes is performed, as needed, by contracted services under the direction of Navy Facilities.

b. Describe storage areas for cages, equipment, supplies, etc.

Drugs are stored locked cabinets in the pharmacy (b)(3) Controlled substances are secured, under double lock. Medical and laboratory supplies are stored in (b)(3)

All staged emergency equipment containing needles, syringes, medications, etc are sealed after each use or inventory.

Equipment used for animal care/training and diving is stored in several equipment sheds located on each pier. Excess equipment, such as the ATC, squeeze cages, stretchers are stored in the Depot building (b)(3)

when not in use.

c. Describe storage areas for flammable or hazardous agents and materials (e.g., disinfectants, pesticides, fuel).

Flammable materials are stored in a dedicated locker adjacent to (b)(3)

Medical gasses are secured in a rack on the side of (b)(3)

Biohazardous material is stored in a dedicated freezer in a fenced in, controlled access area, until pickup from site by contractor.

5. Facilities for Sanitizing Materials [Guide, pp. 153]

Describe for each cage sanitation area its location, the traffic flow pattern (soiled to clean, or in and out) within the facility, and kinds of equipment (tunnel washer, bottle washer, rack washer, etc. and other related equipment such as bedding dispensing units).

No cage sanitation facilities are used. Sea lion transport cages are cleaned and sanitized at enclosure sites.

C. Special Facilities [Guide, pp. 144-146, 150]

1. Specialized Types of Animal Housing

Note specialized types of available animal housing spaces such as barrier, hazard containment (infectious, radioactive, chemical), "animal cubicles" (also known as "Illinois Cubicles", "Horsfal Cubicles," and "animal modules"), or facilities designed specifically for housing certain species such as aquatic or agricultural animals (e.g., barns, feedlots). [Guide, pp. 160-161]

Land based pools, custom inflatable 18' and 20' diameter (b)(3) 20' diameter, are the only specialized animal housing systems in use. Up to five pools may be in use at any one time. No animal cubicles are used in this facility.

2. Surgery [Guide, pp. 144-145]

a. Describe facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery.

Surgery - Surgery suite (b)(3) 317 ft2
Animal preparation - Procedure (b)(3) 524 ft2 (b)(3) Sterile supply
preparation & storage - An autoclave is located in (b)(3) of (b)(3)
Small equipment is in (b)(3)
Surgeon preparation - Sub-sterile (b)(3) opens directly into
the surgery room.
Postoperative care - Animals recover from anesthesia in the procedure room of
(b)(3) After recovery the animal is returned to normal enclosure area.
Follow up care is provided on site.

b. Describe construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and enhance contamination control.

Conventional, painted, sanitizable. There is recirculated, filtered, forced air heating and air conditioning, in all rooms of the Marine Mammal hospital.

(b)(3) (surgery) has the option of positive pressure ventilation when in use. Conventional overhead, shielded fluorescent, auxillary surgery lights in (b)(3) Receptacles are all outdoor grade. Waste anesthetic gases are vented outside. (b)(3) is restricted access area with two routes of entry. Pre-procedure preparation follows routine room sanitation.

3. Other Specialized Animal Use Facilities [Guide, pp. 146-150]

Describe other facilities such as imaging, irradiation, and core behavioral laboratories or rooms. Include a description of decontamination and methods for

preventing cross-contamination in multi-species facilities.

Radiology No specific room dedicated; use treatment, 524 ft² or pier

Aseptic Surgery One, (b)(3) 330 ft²

Animal Procedural Space (b)(3) 545ft²

Diagnostic Lab (b)(3) , 235ft²

Radiation Procedures Conducted at off-site locations in human facilities. Animals transported to human medical centers are transported through special corridors to reduce inappropriate exposure to humans. The room and equipment are draped with plastic protective material prior to movement of the animal onto the equipment. Following the study, the plastic shield is removed and disposed of, and the room thoroughly disinfected prior to use by humans to prevent contamination or possible transmission of disease.

4. Other Animal Support Facilities

Describe other facilities providing animal care and use support, such as food preparation areas, feedmills, abattoirs, etc.

Diet Kitchen Two, (b)(3) 663 ft ² , (b)(3) , 627 ft ² Feed Storage Two, (b)(3) 475 ft ² , (b)(3) 426 ft ²
Feed Storage Two, (b)(3) 475 ft^2 , (b)(3) 426 ft^2
The bulk of the frozen feed fish is stored at (b)(3)
On site fish storage is in dedicated freezers in
(b)(3) $(475 \text{ ft}^2) \text{ and (b)(3)} (426 \text{ ft}^2).$
Non-controlled drugs are stored in locked cabinets in the combined pharmacy and
clinical pathology area in (b)(3)

D. Security and Access Control [Guide, p. 151]

Describe such features as control of entry, perimeter fences, gates, entryways, cameras, guards.

All MMP facilities are located on restricted access military installations. Additional security and access control mechanisms are in effect.

73